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CORE ANALYSIS

On crosswords and jigsaw puzzles: the epistemic limits of the EU Courts and a board of appeal in handling empirical uncertainty

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Abstract

This Article sheds new light on the long-running debate in EU legal studies about how intense the EU judicial review of complex and uncertain assessments requiring specialist knowledge could and should be. It argues that it is necessary to move beyond formulas and concepts hammered out in the judicial statements of reasons and consider how the institutional context affects legal epistemology. How likely is it that the judges form an independent opinion about the probative value of the presented evidence and the soundness of the administration's specialist reasoning? How likely is it that their opinion is reliable? Answering these questions helps appraise the boundaries in which judicial review or proliferating administrative review by partly specialised boards of appeal foster the rule of law understood as the pursuit of non-arbitrariness. The Article examines recent case law of the EU Courts and the Board of Appeal of the European Chemical Agency concerning public health and environmental issues, in which complex and uncertain specialist assessments were prevalent. It contends that, due to institutional limitations of EU adjudicatory bodies, a further expansion of the rule of law in EU decision-making requiring specialist knowledge should be pursued through extra-judicial means fostering transparency, inclusiveness, and accountability.

Keywords: judicial review; administrative review; boards of appeal; scientific uncertainty; legal epistemology

1. Introduction

The EU regulatory and administrative action has grown in scope and complexity, while specialist appraisals and uncertainty have increasingly characterised its empirical basis. This phenomenon affects competition law, financial regulation, and the risk regulation of chemicals, pesticides, or pharmaceuticals. Soon, it will re-emerge in the risk regulation of AI systems.[1] Complexity implies a myriad of factors to be considered and a time and effort-consuming analysis process. Uncertainty adds the impossibility of a single, objectively correct answer, given the limits of specialist knowledge and persistent reasonable disagreements between experts.[2] Uncertainty characterises contemporary science and technology. But it does not invalidate seeking expert

*This Article expresses the personal views of the author and cannot be attributed to the European Ombudsman.

[1]For instance, under Art 7 of AI Act (Proposal for a Regulation of the European Parliament and the Council laying down harmonised rules on artificial intelligence, COM(2021) 206 final), the Commission will decide by means of delegated regulations on the classification of emerging AI technologies as 'high-risk' AI systems, thereby subjecting them to regulatory duties.

[2]AG Emiliou, Case C-389/21 P *ECB v Crédit lyonnais* ECLI:EU:C:2022:844, paras 49–50.

advice or delegating some parts of decision-making to experts. Science can greatly elucidate regulatory problems even if specialists alone cannot and should not solve them.[3]

Value judgements exacerbate uncertainty. For instance, they underlie decisions about required thresholds of proof concerning hazards or risks that justify regulatory responses. Some experts are more precautionary, whereas others expect relatively strong evidence of hazards or risks. Depending on the approach, experts afford different levels of protection to public health, the natural environment or fundamental rights and the interests of the affected industries.[4] A consequence for law and adjudication is blurring the traditional distinction between 'technical discretion' (a matter of 'objective' cognition) and 'political discretion' (a matter of 'subjective' volition).[5] Largely open-ended EU legislative frameworks delegate considerable amounts of such two-fold discretion to executive and administrative decision-makers.[6]

Therefore, the EU Courts have been increasingly facing complex and uncertain empirical appraisals involving specialist knowledge. Legally, they cannot substitute their own assessment for that of specialist administration to indicate what the 'best' outcome of such an assessment should be. However, they must scrutinise the rationality of the decision-making process and the due diligence of the administration. This doctrine is known as the 'duty of care'.[7] It implies that all relevant facts should be considered carefully and impartially;[8] that the evidence should be factually accurate, reliable, and consistent; that this evidence should contain all relevant information; and that this evidence can substantiate the conclusions drawn from it.[9]

Specialist knowledge would undoubtedly assist in enforcing the duty of care, by helping judges recognise which specialist assessments satisfy the above criteria, as well as when and how exactly these assessments are enmeshed with value judgements. Nonetheless, the EU judges are recruited as legal 'generalists' given the wide and diversified jurisdiction of the EU Courts. Therefore, different points of view as to the judicial role regarding specialist appraisals continue to be expressed in the literature. Some believe that such issues remain within the epistemic abilities of

[3]See generally, S Haack, *Defending Science-Within Reason: Between Scientism and Cynicism* (Prometheus Books 2007).

[4]See, G C Leonelli, *Transnational Narratives and Regulation of GMO Risks* (Hart Publishing 2021). See more generally about regulatory science, S Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Harvard University Press 1990); id, *Science at the Bar: Law, Science, and Technology in America* (Harvard University Press 1995); M Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' 62 (2009) Current Legal Problems 242. See the General Court's analysis of how the precautionary approach may permeate the scientific risk assessment phase of decision-making, rather than only subsequent risk management, Case T-77/20 *Ascenza Agro et al. v Commission* ECLI:EU:T:2023:602, paras 340–64.

[5]J Mendes, 'Bounded Discretion in EU Law: A Limited Judicial Paradigm in a Changing EU' 80 (2017) Modern Law Review 443. Some also note the blurring distinction between risk assessment and risk management. See, E Fisher, 'Framing Risk Regulation: A Critical Reflection' 2 (2013) European Journal of Risk Regulation 125. Some argue however that this traditional distinction between cognition (technical discretion) and volition (political discretion) should be maintained. See for instance, AG Léger, Case C-40/03 P *Rica Foods v Commission* ECLI:EU:C:2005:93, paras 45–9; M Prek and S Lefèvre, '"Administrative Discretion", "Power of Appraisal" and "Margin of Appraisal" in Judicial Review Proceedings Before the General Court' 56 (2019) Common Market Law Review 339; A Kalintiri, 'What's in a name? The marginal standard of review of "complex economic assessments" in EU competition enforcement' 53 (2016) Common Market Law Review 1283, 1292–3.

[6]The interpretation of legal concepts such as a 'habitat of a species' (Case C-88/19 *Alianța pentru combaterea abuzurilor* ECLI:EU:C:2020:458) or 'mutagenesis' (Case C-528/16 *Confédération paysanne*, ECLI:EU:C:2018:583) may also require engaging with specialist knowledge. However, this Article concentrates on the judicial or quasi-judicial assessment of complex and uncertain empirical data. See also, A García-Ureta, 'The European Court of Justice's Approach to Scientific and Factual Matters in the Habitats Directive - Between Uncertainty and Precaution' in M Eliantonio, E Lees, T Paloniitty (eds), *EU Environmental Principles and Scientific Uncertainty Before National Courts: The Case of the Habitats Directive* (Hart Publishing 2023) 31, 32–3.

[7]Case C-269/90 *Technische Universität München* ECLI:EU:C:1991:438, para 14; Case T-13/99 *Pfizer* ECLI:EU:T:2002:209, paras 171–2; Case C-12/03 *Commission v Tetra Laval* EU:C:2005:87, paras 38–9.

[8]In some cases, allegations concern conflicts of interests of experts involved in decision-making. See for instance, Case T-594/18 *Pharma Mar v Commission* ECLI:EU:T:2020:512.

[9]Case C-405/07 P *Netherlands v Commission* ECLI:EU:C:2008:613, para 55.

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EU Courts.[10] Indeed, legal epistemologists argue that scientific reasoning is no different from common sense and everyday thinking. It is only more refined,[11] so courts can scrutinise it. Hence, it comes as no surprise that the EU Courts have intensified judicial review in competition law[12] or risk regulation,[13] thus addressing expectations voiced by national courts and litigants,[14] as well as scholars, although they may still apply deference in more novel policy areas.[15] Some also argue that even non-specialist adjudicators 'can easily form an opinion' about the logical consistency of specialist opinions. Therefore, courts can and should engage with science and specialist knowledge through 'consistency' review to maintain the epistemic legitimacy of their rulings.[16] Thus, they can act as 'catalysts' of adequate scientific and empirical basis for regulatory action.[17]

Given the current level of complexity, uncertainty and political controversy surrounding the empirical issues, this optimistic picture is open to question. Consider for example the safety of chemicals of high concern or genetically modified organisms. Can generalist adjudicators form a reliable and informed opinion on how much diligence in such cases should be considered 'due' and which empirical accounts are genuinely consistent? At the same time, it is argued that a deeper engagement with such issues cannot make generalist adjudicators assume the role of 'super-experts', making authoritative statements without adequate credentials.[18] Some are also concerned that more intense judicial review may undermine precautionary assessments made by expert administrators, with concomitant risks to public health and the natural environment.[19] This is all the more so given the restrictive *locus standi* criteria. Because of these criteria, the EU Courts are primarily confronted with scientific information provided or produced by the regulated industries. At the same time, the EU Courts foster a bilateral exchange of such information between the industries and the EU administration 'instead of catalysing inclusive procedures that open regulatory science to public scrutiny'.[20] Some even argue, in a non-EU context, that courts should revert to a deferential standard of review to preserve the expert administration's ability to

[10]See, H Hofmann, 'Interdependencies between Delegation, Discretion and the Duty of Care Regarding Facts' in J Mendes (ed), *EU Executive Discretion and the Limits of Law* (Oxford University Press 2019) 220, 225–6. In the context of competition law, Kalintiri sees the need for the EU Courts to form their own independent appraisal of the probative value of the economic evidence before them. Otherwise, too much value will be automatically and unreflectively attributed to the Commission's evidence. A Kalintiri *Evidence Standards in EU Competition Enforcement* (Hart Publishing 2019) 136–7.

[11]Deirdre Dwyer, *The Judicial Assessment of Expert Evidence* (Cambridge University Press 2008) 104 (citing A Einstein and S Haack).

[12]C-D Ehlermann and M Marquis (eds), *European Competition Law Annual 2009: The Evaluation of Evidence and its Judicial Review in Competition Cases* (Hart Publishing, 2011); M Jaeger, 'The Standard of Review in Competition Cases Involving Complex Economic Assessments: Towards the Marginalisation of the Marginal Review' 2 (2011) Journal of European Competition Law & Practice 295.

[13]P Dąbrowska-Kłosińska, 'Risk, Precaution and Scientific Complexity before the Court of Justice of the European Union' in Ł Gruszczyński and W Werner, *Deference in International Courts and Tribunals* (Oxford University Press 2014) 192.

[14]J Mendes, 'Discretion, Care and Public Interest in the EU Administration: Probing the Limits of Law' 53 (2016) *Common Market Law Review* 419, 430–1.

[15]See, M Ioannidis, 'The judicial review of discretion in the Banking Union: from 'soft' to 'hard(er)' look?' in C Zilioli and K-P Wojcik, *Judicial Review in the European Banking Union* (Edward Elgar 2021) 130.

[16]K Sulyok, 'Science, Legitimacy and the Judicial Function - A Need for More Intrusive Standards of Review' in G Kajtár, B Çali, M Milanovic (eds.), *Secondary Rules of Primary Importance – Attribution, Causality, Standard of Review and Evidentiary Rules in International Law* (Oxford University Press 2022) 84, 98.

[17]J Scott and S Sturm, 'Courts as Catalysts: Rethinking the Judicial Role in New Governance' 13 (2007) Columbia Journal of European Law 565.

[18]E Vos, 'The European Court of Justice in the Face of Scientific Uncertainty and Complexity' in M Dawson, B de Witte, E Muir (eds), *Judicial Activism at the European Court of Justice* (Edward Elgar 2013) 142, 157–60.

[19]G C Leonelli, 'The Fine Line Between Procedural and Substantive Review in Cases Involving Complex Technical-scientific Evaluations: Bilbaína' 55 (2018) Common Market Law Review 1217.

[20]Marta Morvillo and Maria Weimer, 'Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it' 1 (2022) European Law Open 510.

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address hazards and risks before it is too late.[21] Overall, it seems that a search for the appropriate role of courts faced with specialist appraisals is still ongoing and may become even more pressing with the advent of legal disputes concerning the risk regulation of AI or regarding other novel policy areas.

In this context, scholars have recently inquired into the added value of partly specialised boards of appeal (BoAs) set up in certain EU agencies vested with decision-making powers. The BoAs are composed of both lawyers and specialists. They are functionally independent from the agencies. Previous research has revealed far-reaching administrative arrangements securing their independence and their more flexible and informal although still largely adversarial procedures, not falling short of ideals of a fair trial.[22] Nonetheless, the BoAs have struggled with ambiguous legal frameworks and limited resources. Their extra-judicial review has not always met litigants' expectations of greater intensity.[23] The Board of Appeal of the European Chemical Agency (ECHA BoA) appears to be one of the most successful experiments. Being a permanent body within ECHA, it has issued several dozens of decisions in complex matters concerning the risk regulation of chemicals.[24]

A crucial issue concerning how EU adjudicators can and should approach complex and uncertain specialist appraisals still needs to be addressed. How does the nature of specialist knowledge affect the epistemic ability of adjudicators operating in institutional settings such as the EU Courts and the BoAs to form reliable opinions about the probative value of complex and uncertain evidence and the soundness of specialist reasoning? Can we trust that the 'consistency' review by generalist adjudicators is sufficient to enforce the duty of care satisfactorily and protect us against epistemic arbitrariness? How does the somewhat different institutional setting of the BoAs enhance the epistemic perspective of their members? This Article contends that these are crucial questions one should ask oneself while assessing the intensity of judicial or administrative review in specific cases. This way, the debate can move beyond analysing juristic formulas and concepts hammered out in adjudicatory statements of reasons.[25] Moreover, these questions reveal the limits of the expectations that is reasonable to entertain regarding the EU Courts and the BoAs. The point is not to criticise these bodies, but rather to better understand the institutional and procedural confines of their adjudicatory practice, the epistemic perspective resulting from these confines, the 'natural' limits of this epistemic perspective in the face of complex and uncertain empirical assessments, and the inescapably limited extent to which the EU rule of law can be safeguarded through adjudication alone. Thus, these questions shed new light on the long-running debate in EU legal studies about the intensity of EU judicial review and the emerging debate about the added value of administrative review. They invite the reader to gain insights from

[21]For an elaborate argumentation regarding the problems with the 'hard look' judicial review of expert administration see, E Fisher and S A Shapiro, *Administrative Competence: Reimagining Administrative Law* (Cambridge University Press 2020).

[22]M Krajewski, *Relative Authority of Judicial and Extra-Judicial Review: EU Courts, Boards of Appeal, Ombudsman* (Hart Publishing 2021) 129–35. It is also argued, however, that BoAs are inherently different from courts, D Ritleng, 'Boards of Appeal of EU Agencies and Article 47 of the Charter: Uneasy Bedfellows?' in M Chamon, A Volpato, M Eliantonio, *Boards of Appeal of EU Agencies: Towards Judicialization of Administrative Review?* (Oxford University Press 2022) 299. Nonetheless, P Craig, *EU Administrative Law* (Oxford University Press 2018) 281, classifies BoAs as courts.

[23]See the recent challenges to the BoAs' standard of review, Case T-125/17 *BASF v ECHA* ECLI:EU:T:2019:638; Case T-735/18 *Aquind v ACER* ECLI:EU:T:2020:542; Case C-46/21 P *ACER v Aquind* ECLI:EU:C:2023:182; Case T-133/08 *Schräder v CPVO* ECLI:EU:T:2012:430; Case C-546/12 P *Schräder v CPVO* ECLI:EU:C:2015:332.

[24]A Volpato and E Mullier, 'The Board of Appeal of the European Chemicals Agency at a Crossroads' in Chamon, Volpato, Eliantonio (n 22) 84. See also, M Krajewski, 'Judicial and Extra-Judicial Review: The Quest for Epistemic Certainty' in Chamon, Volpato, Eliantonio (n 22) 273, 289–92.

[25]See for instance, Craig who suggests that the EU Courts should develop clearer concepts as to the threshold of proof and the standard of review applicable in specific cases. Craig (n 22), 470–7. Nehl also focuses on the conceptual tools of judicial review. Hans Peter Nehl, 'Judicial Review of Complex Socio-Economic, Technical, and Scientific Assessments in the European Union' in Joana Mendes (ed), *EU Executive Discretion and the Limits of Law* (Oxford University Press 2019) 157.

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the theory of justification and expertise and legal epistemology, helping one realise that long paragraphs of judicial text are not necessarily tantamount to thorough review.

The Article starts from a conception of the rule of law as a constant and never-ending pursuit of non-arbitrariness. It assumes non-arbitrariness to be the normative goal of EU judicial review and other legal mechanisms. It advances a demanding interpretation of the duty of care and assesses different forms of adjudicatory deference in this light (Section 2). Then, it discusses a mixed theory of justification, which is about how we form justified beliefs, and a theory of specialist tacit knowledge, which is about specialist knowledge that cannot be easily conveyed to generalist adjudicators (Section 3). It argues that, to ensure robust protection against potentially arbitrary or unjustified specialist assessments through adjudication, ideally, the adjudicators themselves would have to possess a degree of specialist knowledge. However, acquiring such knowledge requires appropriate institutional conditions. Even if such conditions were satisfied, adjudicatory deference would probably still be unavoidable, but this deference could be overt and informed by independent assessments. Such deference would be compatible with the conception of the rule of law as the pursuit of non-arbitrariness. Subsequently, the Article sheds light on recent case law of the EU Courts issued within the action for annulment (Section 4) and the ECHA BoA (Section 5) concerning hazards and risks to public health and the natural environment. Rather than evaluating or criticising this case law, it attempts to understand the institutional and procedural conditions that co-shape the techniques of review applied to complex and uncertain empirical assessments. These techniques are unavoidably limited in their ability to rule out arbitrariness. Thus, the Article seeks to identify and understand the innate limits of EU adjudication dealing with complex and uncertain specialist assessments. Given the institutional and procedural confines, it may not be realistic to expect EU adjudication to intensify the standard of review even more. A further expansion of the rule of law in EU decision-making requiring specialist knowledge should rather be achieved through developing extra-judicial mechanisms fostering transparency, inclusiveness, and accountability (Section 6).

2. The rule of law as non-arbitrariness and types of deference

Growing expectations towards the EU rule of law prompt questions about the overarching normative goals of this concept.[26] Its traditional understanding, rooted in liberal constitutionalism, is mainly negative and geared towards protecting individual liberty. It introduces dichotomies between the private and the public spheres and between legal norms and discretion. Legal norms constrain the exercise of public power, thereby protecting the liberty of individuals. But beyond the scope of legal norms lies the discretion of public authorities. The liberal doctrine propelled the development of national administrative law. Subsequently, the latter drove the development of EU administrative law.[27]

The negative conception of the rule of law has become out of touch with EU reality. As a teleocracy rather than nomocracy,[28] the EU pursues the goals of closer integration and well-being of EU citizens, including public health and environmental protection. To this end, EU bodies have been vested with extensive regulatory decision-making mandates. However, they are usually not strictly restrained by unambiguous legislative guidance from politically representative bodies.[29]

[26]See regarding the teleological approach to defining the rule of law, M Krygier, 'Four Puzzles about the Rule of Law: Why, What, Where? And Who Cares?' in J Fleming (ed), *Nomos: Getting to the Rule of Law* (New York University Press 2011) 64.

[27]F Brito Bastos, 'Doctrinal Methodology in EU Administrative Law: Confronting the "Touch of Stateness"' 22 (2021) German Law Journal 593; J Mendes, 'The Foundations of EU Administrative Law as a Scholarly Field: Normativism, Functional Comparison and Integration' 18 (2022) European Constitutional Law Review 706.

[28]N Walker, 'The European Public Good and European Public Goods' in Jan Komarek, *European Constitutional Imaginaries: Between Ideology and Utopia* (Oxford University Press 2023) 214.

[29]On a similar development in the United States see, R B Stewart, 'The Reformation of American Administrative Law' 88 (1975) Harvard Law Review 1669.

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More often than not, the EU composite administration hammers out the priorities and balance between competing values, operating within only a general legislative framework, which contains more procedural than substantive norms. At the same time, the rule of law, understood as a fundamental and justiciable value, occupies an increasingly important place in the EU constitutional imagination.[30] In such a political and institutional context, the rule of law should do more than protect individual liberty. Not only should it constrain the exercise of public power negatively, but it should also steer it positively.

Therefore, the EU conception of the rule of law should shift the focus from protecting individual liberty to a more demanding pursuit of the non-arbitrariness of public authorities. Non-arbitrariness is related to the notions of non-domination and predictability.[31] It implies that an exercise of public power is rationally justified by reference to the normative goals of the legal order, pre-defined norms of general application and an accurate account of empirical facts. The law should reduce, as much as possible, the risk of an arbitrary exercise of power, including through adjudication of disputes and other means, such as procedural fairness, transparency, a requirement to issue public guidance about regulatory strategies, the duty to give reasons,[32] and the duty of care.

The duty of care plays a particularly vital role in conceiving the rule of law as the pursuit of non-arbitrariness. It should imply that *each and every step* of reasoning that makes up the account of relevant facts, even those highly intricate and abstruse, should be justified in a rational and accessible way. For instance, experts making precautionary assumptions about the uncertain properties of chemical substances should disclose and justify these assumptions, as well as their interpretive or inferential choices (so that the justification be 'careful') against the potential counterarguments (so that the justification be 'impartial'). This standard may turn out to be quite challenging in practice. As argued further below, considerable amounts of specialist knowledge used in making assumptions and inferential choices remain tacit rather than explicit. Consequently, certain assumptions and inferences may not be fully realised and, at any rate, not easily expressed with words in an intelligible way. Hence, the proposed interpretation of the duty of care appears demanding but indispensable to protect against arbitrary empirical assumptions and inferences, that is, such that are unjustifiable when compared with other options. The proposed conception complements the one offered by Mendes in which the duty of care implies disclosing how cognitive appraisals remain in a dialectical link with volitive appraisals.[33]

Ideally, the pursuit of non-arbitrariness implies the pursuit of the best achievable outcome. Suboptimal outcomes of decision-making can also be considered as instances of arbitrariness, which the duty of care should seek to prevent. Also in this regard the proposed interpretation of the duty of care is more demanding than the standard one. The latter does not imply finding 'the best possible solution', but only aims at ruling out evidently arbitrary decisions.[34] Underlying the less demanding conception may be concerns about the epistemic limitations of judicial review. Courts tend to express the less demanding conception to avoid raising unrealistic expectations

[30]See for instance, L D Spieker, *EU Values Before the Court of Justice* (Oxford University Press 2023).

[31]For an overview of the different conceptions of the rule of law and the rationale of the normatively demanding conception see, A Follesdal, 'International human rights courts and the (international) rule of law: Part of the solution, part of the problem, or both?' 10 (2021) Global Constitutionalism 118, 120–127 (and the rich literature cited therein). For the application of these ideas to the EU institutional context see, D Johnson, 'Institutional Balance as Constitutional Dialogue: A Republican Paradigm for the EU' in M Derlén and J Lindholm (eds), *The Court of Justice of the European Union: Multidisciplinary Perspectives* (Oxford University Press 2018) 115; id, 'The Institutional Balance as an Agent of Transformation in the EU Constitutional Order: Reconciling the Simultaneous Rise of the European Parliament and European Agencies' 6 (2017) Cambridge International Law Journal 202.

[32]G Napolitano, *The Rule of Law* in P Cane, H C H Hofmann, E C Ip and P L Lindseth, *The Oxford Handbook of Comparative Administrative Law* (Oxford University Press 2020) 421.

[33]Mendes (n 14) 450.

[34]AG Maduro, Case C-127/07 *Société Arcelor Atlantique et Lorraine* ECLI:EU:C:2008:292, paras 37–8 (this point was made with regard to legislation).

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towards them. It is intuitive for jurists to conceive of the duty of care as reaching only as far as judicial review can reach since judicial review 'embodies' the rule of law.

However, it seems plausible to 'detach' the duty of care from the limits of judicial perspective. This is because some EU legal mechanisms, such as the BoAs or the European Ombudsman, as well as administrative processes themselves, as argued by Mendes,[35] may pursue the duty of care in areas where the EU Courts must show self-restraint, such as when specialist appraisals are enmeshed with value judgements in convoluted ways. Hence, the duty of care should be considered as a legal principle rather than a binary rule, or in other words, as an 'optimisation requirement'.[36] It should be pursued to the greatest possible extent in given circumstances. Suppose judicial review cannot indicate best possible options due to its institutional limitations.[37] It means that judicial review is insufficient to realise the ideal of the rule of law as the pursuit of non-arbitrariness.[38]

How does the duty of care affect the assessment of judicial deference?[39] Judicial deference does not have to result in tolerating arbitrariness, but it sits uneasily with the pursuit of non-arbitrariness. Nonetheless, deference can imply quite different things. On the one hand, suppose that adjudicators are epistemically able to comprehend and assess successive steps in competing complex and uncertain empirical accounts. These adjudicators may still refrain from imposing their own view on which account appears more convincing. Knowing that either one is sufficiently plausible, they may choose to defer to the party vested with representing the public interest, that is, the public authority. Their deference is 'informed'. If they disclose and justify it, it is also 'overt'. Informed and overt deference seems compatible with the pursuit of non-arbitrariness. It implies a substantial check on the exercise of discretion.

On the other hand, suppose that adjudicators cannot meaningfully engage with an empirical account due to its complexity and uncertainty. As a result, they must completely defer to the public authority. They may invoke doctrinal reasons for deference such as the separation of powers. In such a case, deference is likely to be 'complete'. However, suppose these adjudicators are subject to expectations of 'thorough review', for instance, process-oriented review. In that case, they may still attempt to scrutinise the arguments raised by the applicant against the public authority and, at least, verify whether the administrative file contains some *prima facie* reasonable replies, whether the administration's reasoning appears consistent, and whether the applicant's arguments are not perhaps strong enough to raise serious doubts even with non-specialist adjudicators. In such a case, deference may remain almost or essentially complete, but simultaneously, it will be 'concealed' by long paragraphs of judicial searches for relatively plausible

[35]Mendes (n 5) 469.

[36]In the sense proposed by Robert Alexy in, for instance, *A Theory of Constitutional Rights* (Oxford University Press 2002).

[37]This is why judges have some discretion to establish the required threshold of proof and the intensity of judicial review in deciding whether the threshold has been met. See, Craig (n 22) 470–2.

[38]Mendes presents a similar conception in which she argues: 'judicial review could be better perceived as a second step in the process of shaping normative conduct. In this process, courts, rather than weakening the position of the administration, may collaborate . . . in the achievement of a solution for a complex socio-economic reality. Rather than annihilating the choice between various possible alternatives, courts may structure the exercise of discretion . . . '. This passage can be read as meaning that law, courts, and all public authorities should be united, although performing somewhat different roles, in their pursuit of non-arbitrariness. Mendes (n 5) 462.

[39]This doctrine is usually justified on both epistemic and doctrinal grounds. Epistemic grounds relate to the cognitive superiority of expert administrators, whereas doctrinal grounds refer to the supposed will of the legitimate lawmaker in granting specific competencies to expert agencies. P Daly, *A Theory of Deference in Administrative Law: Basis, Application and Scope* (Cambridge University Press 2012) 8ff. However, it could be argued that doctrinal grounds are merely *ex post* legal rationalisations of more pragmatic epistemic grounds. Moreover, it is disputable whether doctrinal arguments to justify deference could be convincingly used in the EU legal order emphasising the all-encompassing nature of 'legality' review and not based on a clear conception of the separation of powers. See, E Carolan and D Curtin, 'In Search of a New Model of Checks and Balances for the EU: Beyond Separation of Powers' in J Mendes and I Venzke (eds), *Allocating Authority: Who Should Do What in European and International Law?* (Hart Publishing 2018) 53. See, however, Prek and Lefèvre (n 5).

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replies to the applicant's arguments.[40] Complete and concealed deference would be problematic under the normatively demanding conception of the rule of law. It would not necessarily involve a genuine check on the probative value of the presented evidence and the soundness of the contested specialist reasoning.

3. Connoisseurs of science

How to explain in detail the epistemic limits of generalists in dealing with complex and uncertain empirical accounts? On the one hand, the fundamentals of specialist reasoning and fact-finding result from the same standard methods of inquiry (making hypotheses, identifying relevant and reliable evidence that corroborates or falsifies our hypotheses, weighing different pieces of evidence against each other) and making inferences as everyday fact-finding.[41] The scientific method is 'nothing but a refinement of everyday thinking'.[42]

On the other hand, notwithstanding the *syntactical* similarities between expert and non-expert reasoning, the *semantic* content of knowledge possessed by experts and non-experts is very different.[43] Due to the 'refinements', it may be impossible for non-specialists to assess the plausibility of scientific reasoning beyond its internal consistency.[44] A non-specialist may lack the background knowledge to come up with and consider possible alternative steps in a complex and uncertain chain of reasoning to assess the chosen step against the benchmark of the possibly most plausible one. Moreover, scientific reasoning may appear counter-intuitive to 'common sense' (everyday experience or shared beliefs) because of the said 'refinements'.[45]

Haack explains this problem using the analogy of a crossword puzzle. According to her theory of justification, people form reasoned beliefs based on their experiential experience (the analogue of clues in the crossword puzzle) and the support from beliefs they already hold to be true (the analogue of intersecting entries). She argues, 'how reasonable a crossword entry is depends on how well it is supported by its clue and any already-completed intersecting entries, how reasonable those other entries are, independent of the entry in question, and how much of the crossword has been completed. How warranted an empirical claim is depends, analogously, on how well it is supported by experience and background beliefs, how warranted those background beliefs are, independent of the claim in question, and how much of the relevant evidence the evidence includes.'[46]

[40]In the context of legal interpretation of complex statutory instruments, Dyzenhaus has distinguished 'submissive deference' and 'deference as respect'. He argued for judicial 'deference as respect', which would imply that courts would scrutinise and 'take seriously' the specialised tribunal's constructions of statutes and would impose their own interpretations only if those by tribunals were unreasonable. D Dyzenhaus, 'The Politics of Deference: Judicial Review and Democracy' in M Taggart (ed), *The Province of Administrative Law* (Hart Publishing 1997) 279. Also, Daly (n 39) 138–9, argues that even adopting the standard of 'correctness' does not necessarily imply 'judicial imperialism' as courts may still apply 'epistemic deference' recognising the weight of considerations of the first-instance decision-makers. The notions of 'informed' and 'overt' deference, used in this Article, follow the same basic ideas. However, they are intended to emphasise that applying informed deference may involve epistemic challenges.

[41]Dwyer (n 11) 97–107.

[42]A Einstein, as cited in S Haack, 'Trial and Error: The Supreme Court's Philosophy of Science' 95 (2005) American Journal of Public Health S66, S68: '*Einstein A. Physics and reality. Journal of the Franklin Institute, 221, No. 3 (1936). Reprinted in: Bargmann S. Ideas and Opinions of Albert Einstein. New York, NY: Crown Publishers; 1954: 290–323, 290.*'

[43]Dwyer (n 11) 131.

[44]Sulyok considers that even the judicial review of consistency may still be meaningful. Sulyok (n 16).

[45]Dwyer (n 11) 107. See an interesting example regarding 'common-sense' inferences about how DNA is transferred, K Richmond, 'Court of Appeal: DNA Profiling: Transfer and Persistence R v Tsekiri [2017] EWCA Crim 40' 81 (2017) The Journal of Criminal Law 275. See also, Leonelli's comments as to why a common-sense requirement to consider 'all relevant factors' might have unwittingly resulted in imposing on an expert agency the 'right' method of risk assessment, despite scientific reservations. Leonelli (n 19).

[46]S Haack, 'Defending Science – Within Reason' 3 (1999) *Principia: An International Journal of Epistemology* 187, 198. There are many theories of justification. See, R Fumerton, 'Theories of Justification' in P K Moser (ed.), *The Oxford Handbook*

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As regards the review of uncertain scientific assessments, such as that at the EU level, generalist adjudicators receive written and oral 'clues' from the parties during the review proceedings. They may also conduct their own research. However, their crossword puzzles are usually, most likely, nearly or entirely empty. They cannot assess a specialist proposition by seeing how well it fits other related propositions. As Haack puts it, 'When a lay person, or even a scientist from another speciality, tries to judge the quality of evidence for a scientific claim, he is liable to find himself in the position of the average American asked to judge the reasonableness of entries in a crossword puzzle where, though some of the clues are in pidgin English, the solutions are all in Bengali, and require a knowledge of Islam'.[47]

The even more prevalent concern is whether generalist adjudicators can form or assess justified inferences when confronted with conflicting evidence and expert appraisals provided by the parties or when confronted with expert criticism of a court-appointed expert witness. First, experts are prone to mistakes, bias, and cognitive defects like other humans.[48] Second, the reasons for experts to disagree are often related to scientific uncertainty, that is, 'a potential for error in drawing an inference'.[49] Walker provides a typology of reasons for scientific uncertainty. Scientific uncertainty occurs because experts disagree about choosing an adequate conceptual framework to steer their inquiry and circumscribe the range of empirical factors that should be considered. They may disagree about the 'acceptable imprecision' of the chosen methodology. They also disagree about the appropriate size, generalisation and extrapolation from the selected sample. Moreover, they disagree about models used to predict values for some variables based on values for others. Finally, they may have differing views in interpreting causality that would explain associations between different events.[50]

Can adjudicators possess the necessary background knowledge to engage with this kind of uncertainty meaningfully or, in other words, to fill in at least some of the entries in their crossword puzzles? A theory of expertise developed by Collins and Evans suggests it is possible, but at the same time, this theory points to another significant obstacle related to the twofold structure of knowledge.

Collins and Evans conceptualise different degrees of expertise. The highest degree is *contributory expertise,* which allows an expert to contribute to a specific field of knowledge by practising science and making scientific advancements. This expertise is formed by specialist *explicit* and *tacit* knowledge.[51] Explicit knowledge can be transferred through intermediaries (such as text), whereas *tacit* knowledge can only be acquired by frequent interactions or 'hanging around' those who possess it. Tacit knowledge is 'things you just know how to do without being able to explain the rules for how you do them'.[52] It follows from Collins and Evans' theory that tacit knowledge comprises, among other things, an 'acquired intuition' or a 'professional feeling'

of Epistemology (Oxford University Press 2005) 204. Thanks to its mixed character, Haack's theory of 'foundherentism' (combining foundationalism and coherentism) seems particularly persuasive and illustrative in elucidating the interplay between the contested specialist information received by the adjudicators during the trial from the parties and their own 'background' knowledge that they possess or lack, but which seems indispensable for performing 'thorough' review. Besides, Haack herself has extensively analysed the consequences of her theory for court decision-making. See many themes discussed in S Haack, *Evidence Matters: Science, Proof and Truth in the Law* (Cambridge University Press 2014).

[47]Haack (n 3) 236.

[48]Daly (n 39) 82ff and the literature cited.

[49]V R Walker, 'The Myth of Science as a "Neutral Arbiter" for Triggering Precautions 26 (2003) Boston College International and Comparative Law Review 197, 204.

[50]Ibid., 205–11.

[51]H Collins and R Evans, *Rethinking Expertise* (The University of Chicago Press 2007) 13–14. As they note, 'mastering a tacit knowledge-laden specialism to a high level of expertise, whether it is car-driving or physics, ought, then, to be like learning a natural language – something attained by interactive immersion in the way of life of culture rather than by extended study of dictionaries and grammars or their equivalents.' Ibid., 23. See also, H Collins, *Tacit and Explicit Knowledge* (The University of Chicago Press 2010).

[52]Collins and Evans (n 51) 13. On 'hanging around', Collins (n 51), 87.

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coming from experience. Among other things, it helps assess the methodological robustness of scientific studies or reasoning – including the plausibility of inferences, extrapolations, generalisations, predictions, and conclusions shrouded in scientific uncertainty – and distinguish more convincing and less convincing scientific arguments. As opposed to '*ubiquitous tacit knowledge*' – such as knowledge of how to read and write, ride a bike, or predict causal events in everyday life – specialist tacit knowledge is reserved for the members of expert communities. Vast amounts of knowledge regularly used to perform complex and uncertain intellectual operations exist only in a tacit form. Tacit knowledge is transferred to the adepts of science through socialisation, trials and errors, and observations of scientific practices rather than through written or spoken words alone. It is even arguable that most specialist knowledge, stored in experts' minds, exists in a tacit form only. A considerable part of specialist knowledge remains tacit because the members of the relevant epistemic community do not see a need to make it explicit. For their purposes, it is sufficient in the tacit form (such as the methodological and quality standards of legal research, which for a long time remained largely tacit[53]). At the same time, tacit knowledge may be so complex that it would require disproportionate resources to make it explicit.[54]

Nonetheless, it is possible to acquire specialist explicit and tacit knowledge without engaging in the collective practices of science and without making contributions to the field or scientific advancements. This way, one can acquire a somewhat lower level of expertise, that is *interactional expertise,* allowing one to interact with experts and speak their language.[55] Thanks to this level of expertise, one can be a liaison with another expert field or general population (by engaging in the popularisation of science). Interactional expertise may take the form of '*connoisseurship*' that allows expertly judging experts' outputs, like a connoisseur judging paintings without having ever made one herself.[56] This interactional expertise can be acquired to different degrees but also requires interactions with the relevant expert community. As Collins puts it, 'drawing on the tacit knowledge of the collectivity through language alone is often not the most efficient way to do it … a person who has taken part in both conversations and practical activities is likely to be further ahead in the acquisition of collective tacit knowledge than a person who has been exposed to words alone'.[57] In other words, it may be a good idea for those trying to become connoisseurs of the work of a relevant community to 'hang around' their members, interact with them or observe them at work.

Overall, to ensure the non-arbitrariness of complex and uncertain empirical assessments, those tasked with their independent review should ideally be able to rely on their own specialist knowledge – including tacit knowledge – rather than only the explicit information provided by the parties during judicial proceedings. In particular, specialist knowledge, including specialist tacit knowledge, would enable the adjudicators to form independent and, ideally, relatively reliable opinions about the probative value of complex and uncertain evidence and the soundness of specialist reasoning. But crucially, to acquire the tacit knowledge necessary to reach 'scientific connoisseurship', the adjudicators would have to come from relevant expert communities or, at least, frequently interact with their members.

However, the primary goal of EU judicial review is to ensure the correct interpretation of legal provisions, the uniformity of legal principles across policy areas, and a harmonisation of EU legal cultures. Therefore, generalist judicial review may not be sufficient, in and of itself,

[53]M Snel, 'Making the implicit quality standards and performance expectations for traditional legal scholarship explicit' 20 (2019) German Law Journal 1.

[54]Collins (n 51) 94–5. Generally on the transfer of tacit knowledge see, in particular, ibid, 85ff. This paragraph of the Article summarises and interprets the complex theory advanced by Collins and Evans (n 51) and Collins (n 51).

[55]Ibid., 136.

[56]Collins and Evans (n 51) 58–9. As the authors note, connoisseurs also need practical experience, but it is the experience of judgement 'rather than experience of the skill itself'. Notably, connoisseurs often have the ability to speak two languages, e.g. the language of both painters and their (non-expert) clients.

[57]Collins (n 51) 137.

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to simultaneously secure the non-arbitrariness of complex and uncertain empirical assessments requiring specialist knowledge. Too many different orders for just one cook. This is why the emergence of the partly specialised BoAs vested with a sector-specific jurisdiction is a noteworthy development in the EU legal order.

Nonetheless, some argue that generalist courts and judicial review may still play a meaningful role by focusing on questions that seem epistemically 'easier'.[58] Scott and Sturm argue that courts could, among other things, act as 'catalysts', scrutinising whether the informational base underpinning the impugned decisions is comprehensive, reliable and/or sound. Courts should focus on elaborating and enforcing procedural rules, including the involvement of relevant actors, such as specialist risk assessors. They should also check whether the empirical basis contains all necessary elements and whether there have been any 'manifest errors' of assessment.[59] Tackling specialist assessments from the procedural angle seems more feasible for courts than delving into the complex and uncertain substantive appraisals head-on.

But how should courts proceed if the direct object of the legal challenge is an alleged error in a substantive specialist assessment and the legal basis for this challenge is the duty of care? Sulyok points to judicial techniques that she calls 'hybrid'. In her view, as 'located on the interface of scientific and legal inquiry, they provide the basis for reasoning that neatly falls within the epistemic competence of legally trained judges. In essence, the primary focus of these benchmarks is on the *reasoning* of the risk assessor … Judges who engage in such an argumentative style, should only decide about the legally appreciable features of science-based reasoning, such as its reasonable and coherent nature or consistency'.[60] Sulyok argues that such hybrid techniques are workable, pragmatic, and efficient.

What does 'consistency' mean? As Haack aptly analyses, formal logical consistency means the absence of contradictions, but 'consistency' is often used in a broader sense 'connoting the mutual compatibility of a set of propositions'. 'Consistent' or 'coherent' can also mean 'intelligible' and 'well-ordered', as well as treating similar cases in a similar way, so 'fair'.[61] However, a largely mistaken account of reality can be consistent: free from contradictions, made of mutually compatible propositions, intelligible, well-ordered, and consistent in committing the same mistake repeatedly. Someone with specialist background knowledge might discern broader inconsistency between such an account and other well-established specialist propositions and accounts, but as already said, the access to or possession of such background knowledge may constitute a challenge for non-specialists.[62]

Hence, the said procedural or hybrid judicial strategies, focused on consistency, may not sufficiently address the risk of arbitrariness in the reality of contemporary EU litigation, in which the substance of specialist appraisals is increasingly often challenged in courts. The main problem lies in the difference between what appears 'consistent' and what is genuinely 'reliable'. Due to their innate limitations, courts may be forced to stop at consistency without delving into reliability. Therefore, it is no longer sure to what extent they can be successful 'catalysts' of sound empirical basis for regulatory and administrative action.

One can think of another helpful metaphor to clarify the difference between scrutinising, on the one hand, the internal consistency of specialist reasoning and, on the other hand, the compatibility

[58]See, Scott and Sturm (n 17); Sulyok (n 16); Vos (n 18).

[59]Scott and Sturm (n 17) 582–6.

[60]Katalin Sulyok, *Science and Judicial Reasoning: The Legitimacy of International Environmental Adjudication* (Cambridge University Press 2020) 352–3. However, Sulyok also admits that, even when using hybrid techniques, judges must also engage to certain extent with substantive issues. Ibid., 356.

[61]S Haack, 'Coherence, Consistency, Cogency, Congruity, Cohesiveness, &c.: Remain Calm! Don't Go Overboard!' 35 (2004) New Literary History 167, 168–9 and 171–2.

[62]Haack (Ibid., 175), in general, sees the main problem of 'coherentist' theories of justification in them not giving consideration to a person's sensory and introspective experience in the justification of her empirical beliefs (such theories may justify 'a vicious circle of reasons').

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of this reasoning with background specialist knowledge. Imagine a jigsaw puzzle comprising a few thousand pieces and displaying the painting on the ceiling of the Sistine Chapel. Imagine that, although the *picture* on each piece of this puzzle is obviously *unique*, the *shape* of each piece is *not unique*.[63] Many pieces belonging to different places in the puzzle have the exact same shape, although they present different pictures. Someone putting together this puzzle will undoubtedly focus on the pictures, which are unique, using the shapes as subsidiary clues where the neighbouring pieces contain very similar pictures (think of twenty bright blue pieces making up the sky above Adam and Eve). However, what if someone is forced to put together this jigsaw puzzle with dim light, being able to recognise the shapes, but not the pictures? Putting this puzzle together in these circumstances, relying primarily on the shapes, is not impossible, but prone to errors and not the most efficient way of proceeding. We can later realise that the face of God has been put upside down, those of Adam and Eve have been switched, and the pieces of the blue sky have been put more or less next to each other, but not in the right places.

Arguably, scrutinising the internal consistency of specialist reasoning without relying on specialist knowledge is like putting together a vast and complex jigsaw puzzle based on the shapes without clearly seeing the pictures. The shapes in this metaphor are internal consistency, while the pictures and the big picture on the cover of the box are specialist knowledge.

4. The upper limits of judicial review

A. Institutional and legal contexts

The following two sections shed more light on how EU adjudication engages with complex and uncertain scientific appraisals. They analyse the likelihood that, in the specific institutional setting of the EU Courts and the ECHA BoA, the adjudicators independently evaluate the probative value of complex and uncertain evidence and the soundness of specialist reasoning.

The institutional setting of EU Courts does not seem strongly conducive to judges' acquiring specialist knowledge, especially tacit, necessary to develop 'scientific connoisseurship'. First, due to their generalist composition, the empirical evaluations by the EU Courts seem to be informed more by ubiquitous than specialist tacit knowledge. There is no fully-fledged specialisation of EU judges and their supporting staff in specific policy areas.[64] This limitation stems from the EU's political and constitutional structure. Introducing specialisation would necessarily involve creating judicial portfolios (in competition law, risk regulation, civil service law, etc.) distributed among the Member States, which nominate candidates to the EU judicial posts. The existence of such judicial portfolios could lead to political disputes, complicating judicial appointments. Specialisation may also result in an emergence of narrow epistemic communities within the courts, with concomitant risks for the uniformity of case law across different policy fields.

Second, the reasoning of EU Courts and the intensity of judicial review in most types of proceedings is conditioned by the arguments, evidence and its elucidation provided by the parties (usually in a written form),[65] no matter how intense the standard of judicial review is officially proclaimed. In such an essentially adversarial setting,[66] the applicants specify the subject matter of

[63]This seems to be rarely the case, but this is just a thought experiment.

[64]See, however, regarding temporary, partial and internal specialisation within the General Court, F Clausen, 'Quelle place pour la spécialisation au sein des juridictions de l'Union européenne' in D Dero-Bugny and A Cartier Bresson, *Les reformes de la Cour de Justice de l'Union européenne* (Bruylant 2020) 131. See also other arguments in favour of specialisation in U Öberg, M Ali and P Sabouret, 'On Specialisation of Chambers at the General Court' in Derlén and Lindholm (n 31) 211.

[65]See for instance, Case T-639/20 *TIB Chemicals v Commission* ECLI:EU:T:2023:374, for instance, paragraphs 99 and 103, in which a relatively thorough engagement with science seemed enabled by the submissions by the Commission and interveners.

[66]The adversarial procedural model does not characterise all the systems of administrative justice in the EU. See for instance, W Köck and T Markus, 'Legal Approaches to Scientific Uncertainty in Germany' in Eliantonio, Lees and Paloniitty (n 5) 163, 172-176. The largely adversarial setting, chosen by the EU judges in the early days of European integration in Case 46/59 *Meroni v High Authority* ECLI:EU:C:1962:44, has not been unambiguously enshrined in EU procedural law, but is

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proceedings (the contested act, the pleas in law) and carry the burden of persuading the EU judges that the contested act is vitiated by a breach of law, including a violation of the duty of care or a manifest error of assessment.[67] If the parties, or rather their lawyers, fail to advance appropriate pleas in law or fail to substantiate them, it may be that an objectively faulty or unlawful EU measure will remain in force.[68]

Third, the EU Courts do not engage in independent fact-finding, including by appointing independent experts or organizing a hearing of partisan experts,[69] although the rules of procedure allow for such procedural measures.[70] At oral hearings, the judges interact with lawyers only.[71] This procedural setting fosters an efficient use of judicial resources and a reasonable duration of proceedings. It also safeguards the decision-making autonomy of the challenged EU institutions and bodies. It prevents the EU Courts from 'taking over' the primary responsibility for decision-making.[72] Moreover, allowing partisan or court-appointed experts to appear in the courtroom could generate an infinite regress. How would generalist judges assess subsequent substantive allegations against the expert testimony? By appointing further experts?

Apart from this institutional and procedural setting, one should also keep in mind the characteristics of the applicable EU substantive legal frameworks. These frameworks lay down conditions where EU institutions and bodies may undertake regulatory action, providing indications regarding this action's contents as well. However, they do so utilising under-determined concepts, the interpretation of which requires reaching out to specialist knowledge such as a 'risk to human health or the environment'[73] or 'active substance'.[74] Such legal concepts bind and orient the exercise of technical and political discretion only to a relatively limited extent.[75] This little 'steering capacity'[76] of EU substantive law is why specialist appraisals constitute

largely taken as 'natural' for judicial bodies. Barents argues that a system leaving more discretion to the EU judges as to raising substantive pleas in law and arguments of their own motion would be conceivable and, perhaps, desirable to uphold the rule of law. R Barents, 'EU Procedural Law and Effective Legal Protection' 51 (2014) Common Market Law Review 1437.

[67]The EU Courts may identify a manifest error of assessment, if 'the evidence adduced by the applicant [is] sufficient to make the factual assessments used in that measure implausible'. Case T-584/13 *BASF v Commission* ECLI:EU:T:2018:279, para 94. For an example see, Joined Cases T-337/18 and T-347/18 *Laboratoire Pareva & Biotech 3D v Commission* ECLI:EU:T:2021:594, paras 130-131. Assessing the lawfulness of legal acts which affect not only their addressees, but also multiple third parties and society in general in such an adversarial setting may give rise to doubts. Procedural errors by one party can tip the scales in favour of the other with concomitant risk for the public interest. For instance, Leonelli discusses a case in which a wrong defence strategy by the Commission might have led to the EU Courts' inadvertently quashing the prudential risk assessment of a risky chemical substance. See Leonelli (n 19).

[68]The EU judges may only raise on their own motion pleas in law relating to 'public policy' which include the lack of competence to adopt the impugned act and some infringements of essential formal and procedural requirements. Case C-122/16 P *British Airways v Commission* ECLI:EU:C:2017:861, paras 81 and 87–90; Case C-436/19 P *Abaco Energy v Commission* ECLI:EU:C:2020:606, paras 68–9, 75–6 and 85.

[69]See an interesting account, J Padilla, 'An Economist's Perspective on the EU Competition Judicial Review Process' available at https://events.concurrences.com/IMG/pdf/an_economists_perspective_on_eu_competition_procedure_09052021.pdf. However, the application of 'manifest error' test in competition law cases may suggest that the judges have already possessed some degree of independent background knowledge although the standard of review in this field is also fluctuating and not entirely clear. See, Kalintiri (n 5) 1299–302 and 1306–12.

[70]Rules of Procedure of the General Court of 4 March 2015 (OJ 2015 L 105/1), Title III, Chapter 6, Section 2 'Measures of Inquiry'.

[71]Ibid., Art 51.

[72]See, E Barbier de la Serre and A-L Sibony, 'Expert Evidence Before the EC Courts' 45 (2008) Common Market Law Review 941; A Fritzsche, 'Discretion, Scope of Judicial Review and Institutional Balance in European Law' 47 (2010) Common Market Law Review 361.

[73]Art 44(2) REACH which lays down the main condition for subjecting chemical substances to further evaluation.

[74]Case T-611/18 *Pharmaceutical Works Polpharma v Commission* ECLI:EU:T:2021:241, paras 210–18.

[75]Unlike in certain European administrative law doctrines, as discussed in Mendes (n 5), in EU law administrative discretion also applies to the determination of the factual basis for administrative action. Case T-13/99 *Pfizer v Commission* (n 7), para 168.

[76]Nehl (n 25) 170.

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a significant challenge for law-based adjudication. Rather than only applying clear-cut substantive legal criteria, EU adjudicators must also verify whether the contested empirical appraisals are 'objectively' plausible or even correct.

Last but not least, the precautionary principle should be kept in mind. It is a general principle allowing regulatory action to address uncertain risks even if conclusive evidence of these risks is unavailable, which is often the case in regulatory science.[77] This principle is seen as a crucial legal tool enabling decision-makers and the courts to reach decisions, including on regulatory action addressing hazards and risks despite scientific uncertainty. Undoubtedly, it has an intuitive appeal. Some proponents of this principle suggest that judicial review should not even aim at setting out minimum threshold conditions for when this principle can be triggered. In this view, judicial review should only concern itself with whether the impugned regulatory action has been based on any scientifically verified proposition.[78] Why should courts apply such self-restraint? They may have a 'natural' propensity towards searching for 'hard evidence', rooted in one of the central tenets of the liberal rule of law. According to this tenet, individual freedom of action (and business) may be restrained only when that course of action proves clearly and undoubtedly necessary to protect other normative goals, following the principle of proportionality. Therefore, a snowball effect could be expected to follow. In the long run, courts would require increasingly conclusive evidence of hazards and risks, undermining the precautionary approach.

However, some scholars have pointed out the many difficulties inherent in the precautionary principle. Precautionary reasoning tends to focus on worst-case scenarios, ignoring that the probability of some risks is low. Hence, it may lead to a loss of potential gains from innovation. Preventing some risks may also lead to the emergence or re-emergence of others. Therefore, an overly precautionary approach may also lead to arbitrariness by providing normative support to regulatory action that would address purely hypothetical risks or lead to other adverse consequences.[79] For this reason, as argued, the precautionary principle cannot be a blank check to undertake 'risk management' measures addressing purely hypothetical, theoretical and unproven risks.[80] Even proponents of the precautionary approach could concede that only the risks underpinned by some 'solid', 'convincing' or 'reasonable' empirical basis can justify a regulatory response,[81] which implies that some minimum threshold conditions must unavoidably exist and, arguably, be amenable to judicial review. However, the problem lies in scientific uncertainty. Assessing where the minimum threshold lies may involve considerable technical and political discretion and require the epistemic capacity to distinguish between plausible and implausible scientific assessments.

B. Still catalysts

The above institutional, procedural, and legal context conditions how EU adjudicators engage with complex and uncertain specialist appraisals. This context should be kept in mind while

[77]Case T-13/99 *Pfizer* (n 7), paras 113–15 and 139.

[78]G C Leonelli, 'Balancing public health and environmental protection and economic stakes? Bayer CropScience and the Court's defence of the EU socially acceptable risk approach' 58 (2021) Common Market Law Review 1845, 1870.

[79]G Majone, 'What Price Safety? The Precautionary Principle and its Policy Implications' 40 (2002) Journal of Common Market Studies 89; R B Stewart, 'Environmental Regulatory Decision Making under Uncertainty' 20 (2002) Research in Law and Economics 71; C Sunstein, 'Beyond the Precautionary Principle' 151 (2003) University of Pennsylvania Law Review 1003.

[80]Among others, B J Preston, 'The Judicial Development of the Precautionary Principle' 35 (2018) Environmental and Planning Law Journal 123, 133–136.

[81]Among others, Leonelli (n 78), 1867, agrees with that 'all that is necessary for the EU institutions to take action is *solid and convincing evidence* which may *reasonably* cast doubt as to compliance with the approval criteria' (emphasis added), although at the same time, she doubts that it is possible and appropriate to conceive of 'a specific threshold of risk' and 'specific level of scientific certainty ... required for EU risk managers to take precautionary action'.

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analysing court rulings with an eye to understanding the intensity of review and evaluating whether the court could have been realistically expected to do more.

In some cases, specific pleas in law raised against contested EU legal acts and relating to the underlying specialist opinions make it possible for the EU Courts to eschew delving deep into the substance of these opinions. Instead, the courts focus on ensuring that the impugned regulatory or administrative action is indeed underpinned by adequate empirical evidence provided that the parties offer relevant pieces of evidence and its persuasive elucidation. In such cases, the EU Courts can still play the role of 'catalysts', to some extent, by ensuring that regulatory action is underpinned by adequate scientific assessment.

For instance, a recent case concerned the authorisation of specific uses of chromium trioxide under the 'REACH' Regulation.[82] The Commission can authorise the use of substances 'of very high concern', such as chromium trioxide, based on the opinions of the ECHA's specialist Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC). The legal conditions are that either 'the risk to human health or the environment from the use of a substance arising from the intrinsic properties [of this substance] is adequately controlled' or 'it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and ... there are no suitable alternative substances or technologies'.[83] Although REACH lists factors that should be considered,[84] analysing whether the legal conditions are fulfilled is characterised by considerable discretion delegated to RAC and SEAC and then to the Commission.

In this case, the Commission considered that the risk to human health of the proposed uses of chromium trioxide was not adequately controlled, but it authorised this substance nonetheless, holding that socio-economic benefits outweighed the risks. However, the Parliament relied on the opinions of ECHA committees to argue that the company applying for the authorisation had provided unrepresentative and unreliable data regarding the risks. In the Parliament's view, logically, the Commission could not properly assess whether potential benefits outweighed the risks, since the level of risk was uncertain, as reflected in the Commission's decision to impose additional conditions and monitoring arrangements on the company. The Commission counter-argued that uncertainty had not prevented it from establishing that one of the legal conditions for authorisation had been met.

In this case, the Court was not deciding between competing empirical accounts but was called on to ascertain the meaning and conclusions flowing from the scientific opinions. It concluded that RAC had explicitly acknowledged too many shortcomings of the information provided by the company for the Commission to hold that the legal condition for the authorisation had been met.[85] Similarly, as followed from SEAC opinion, the Commission had failed to ascertain that there were no suitable alternatives to the substance.[86] Overall, the Court's contribution consisted in ensuring that regulatory action at issue was genuinely conditioned and oriented by scientific

[82]Case C-144/21 *Parliament v Commission* ECLI:EU:C:2023:302.

[83]Art 60(2) and (4) of Regulation 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396/1, 30.12.2006.

[84]Section 6.4. Annex I and Art 60(4) REACH.

[85]Case C-144/21 *Parliament v Commission* paras 61–86 (n 82).

[86]Ibid., paras 104–31. See another instance, in which the General Court focused on the rationality of decision-making process and its detailed elements by investigating the contents of the administrative files and scientific opinions and literature contained therein, Case T-611/18 *Pharmaceutical Works Polpharma v Commission* ECLI:EU:T:2021:241, para 196–7 and 239ff. However, this ruling was quashed on appeal on the point of law. Case C-438/21 P *Commission v Pharmaceutical Works Polpharma* ECLI:EU:C:2023:213. See also, Case T-837/16 *Sweden v Commission* ECLI:EU:T:2019:144, paras 52ff, in particular para 86ff. In that case, the EGC disagreed with the Commission's underestimating the level of uncertainty regarding the existence of alternatives to a risky substance, by pointing out to the available evidence that had been disregarded. See also regarding an example of importance of the elucidation of scientific information provided by the parties, Case T-122/20 and T-123/20 *Sciessent v Commission* ECLI:EU:T:2022:712, paras 76–9.

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conclusions. Thus, the Court structured the discretion of risk managers by engaging with the output of risk assessors.

C. Between consistency and reliability

Some cases appear more challenging inasmuch as applicants increasingly contest the substance of scientific opinions, pointing out alleged inconsistencies or underestimated scientific studies that should allegedly change the overall empirical assessment. Often, the applicable law does not determine the required type of evidence, leaving the assessment of its probative value to the decision-makers. In such cases, adjudicators may attempt to apply review techniques based on ubiquitous rather than specialist knowledge, such as calling on the challenged expert administration to explain its assessments intelligibly, consistently and prima facie convincingly to non-specialists. In particular, EU judges scrutinise the contested specialist reasoning in search for 'comprehensive links', that is, links that appear intelligible and logical.[87] EU judges may point out inconsistencies and deficiencies in the parties' submissions[88] and verify compliance with pre-established specialist guidelines and standards.[89] Most importantly, they may require the applicant to comprehensively justify why and precisely how an allegedly missing factor should have changed the overall assessment. Thus, they signal that the burden of persuasion in EU judicial review rests on the applicant's shoulders.[90] The applicants cannot expect to be successful by simply indicating a 'weakness' in the EU administration's reasoning. They must fully elaborate on this weakness and elucidate the judges as to how it should change the conclusion. In practice, EU judges frequently find the applicants' arguments to be merely general assertions that do not convince them of manifest errors in scientific reasoning.[91]

Scrutinising the minutiae of logical links in contested scientific reasoning may prove quite potent and, at any rate, perfectly sufficient to solve many cases in which specialist assessments are challenged. This strategy is recommended by Sulyok[92] and arguably conforms with the conception of courts as 'catalysts' by Scott and Sturm.[93] But it does not perfectly secure against arbitrariness given the contemporary complexity and uncertainty of empirical issues emerging in EU litigation. It is arguably based more on ubiquitous than specialist knowledge, so it rules out specialist tacit knowledge. In most challenging cases, it may resemble Haack's analogy of solving an intricate and abstruse crossword puzzle relying on clues and ubiquitous common-sense ways of reasoning only, where the entries are supposed to be given in a foreign language and reflect a system of knowledge

[87]The judicial review of opinions issued by scientific committees of the European Medicines Agency is limited to 'the lawfulness of their operation, and... the internal consistency and reasoning of the PRAC's recommendation and the CHMP's opinion. With regard to the latter element, the courts may only examine whether the recommendation and the opinion contain a statement of reasons from which it is possible to ascertain the considerations on which the recommendation and opinion are based, and whether they establish a comprehensible link between the medical or scientific findings and their conclusions'. Case T-783/17 *GE Healthcare v Commission*, paras 51, 66–75; Case T-189/13 *PP Nature-Balance Lizenz v Commission* ECLI:EU:T:2014:1056, paras 52, 54ff; Case T-672/14 *Dr August Wolff v Commission* ECLI:EU:T:2016:623, paras 142–64; Case T-556/20 *D&A Pharma v Commission* ECLI:EU:T:2022:111, paras 188–236; see also Case T-303/16 *Mylan IRE Helathcare v Commission* ECLI:EU:T:2022:25, paras 135–41. See also other cases in which the General Court seems to be verifying whether there is a 'comprehensive link' in scientific assessments, Case T-115/15 *Deza v Commission* ECLI:EU:T:2017:329, para 163–202; Case T-400/17 *Deza v Commission* ECLI:EU:T:2018:712, paras 44–58; Case T-207/18 *Plastics Europe v ECHA* ECLI:EU:T:2020:623, paras 112ff; Case T-201/13 *Rubinum v Commission* ECLI:EU:T:2015:311, paras 73–8.

[88]For instance, Case T-472/19 *BASF v Commission* ECLI:EU:T:2020:432, paras 75–81; Case T-115/15 *Deza v Commission*, paras 193–7.

[89]Case T-177/19 *Exxonmobil Petroleum & Chemical v ECHA* ECLI:EU:T:2021:336, paras 126–34.

[90]For instance, Case T-629/20 *Delifruit v Commission* ECLI:EU:T:2022:448, para 49. See also, Case T-719/17 *FMC Corporation v Commission* ECLI:EU:T:2021:143, paras 165–70.

[91]Case T-115/15 *Deza v Commission*, paras 198-199; Case T-472/19 *BASF v Commission* (n 88), paras 77–9; Case T-303/16 *Myre IRE Healthcare v Commission* ECLI:EU:T:2022:25, paras 61–3.

[92]Sulyok (n 16) 98.

[93]Scott and Sturm (n 17). See also, Vos (n 18).

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utterly alien to the person solving the puzzle. It may also resemble the metaphor of assembling a complex jigsaw puzzle based on the non-unique shapes of the pieces only, not seeing the pictures.

Take a recent case that concerned updating the entry of bisphenol A as a candidate for 'a substance of very high concern', the use of which would be subject to prior authorisation under REACH on account of endocrine disrupting properties. The legal condition for identifying candidate substances was that there exists 'scientific evidence of probable serious effects to . . . the environment', which gave rise to 'an equivalent level of concern' to the effects of some other substances considered as being of very high concern.[94] The company placing this substance on the market alleged, among other things, that ECHA had wrongly disregarded some reliable studies dispelling the concerns. ECHA applied a 'weight-of-evidence' approach, which involved considerable specialist discretion, and which implied that 'evidence from multiple independent sources of information is considered, while the information from each single source alone is regarded insufficient to support that hypothesis or finding'.[95] The General Court held that it could find a manifest error of assessment 'only if ECHA completely and wrongly disregarded a reliable study, the inclusion of which would have altered the overall assessment of the evidence so that the final decision would have been implausible'.[96] Then, the General Court meticulously verified the contents of the ECHA decision and its support document to ensure that the reasoning was intelligible, appeared consistent, and offered plausible reasons for certain studies being considered relevant and others irrelevant. It also held that the applicant had not demonstrated how the result of the weight-of-evidence analysis should be altered.[97]

However, a reader of the judgement may be uncertain to what extent the reasons provided by the General Court in this and similar cases imply an independent assessment of the substantive correctness or at least plausibility of the contested specialist reasoning. It is challenging to deduce the level of such an independent assessment from the judicial statement of reasons. Assessing methodological strengths and weaknesses of specific scientific studies might have required considerable specialist knowledge, including tacit knowledge. Even if the General Court was convinced that ECHA's weight-of-evidence approach appeared plausible, it remains unclear to what extent this judicial assessment was prone to errors. The Court's reasoning was probably based mainly on ubiquitous reasoning, bereft of tacit knowledge stemming from years of experience in expertly judging the reliability of similar scientific opinions. In particular, the weight-of-evidence exercise, in this case, encompassed multiple studies applying various methods, having different core objectives and different weaknesses, thereby arguably presenting a varying probative value. More precisely, the weight-of-evidence approach is applied when 'the information from a single piece of evidence alone is not sufficient to fulfil an information requirement' under REACH. 'This could be, for example, due to clear deficiencies in one of the existing studies' or where 'individual studies provide different or conflicting conclusions'. The weight assigned to the different pieces of evidence 'depends on factors such as the quality of the data, consistency of results, nature and severity of effects, and relevance of the information'. Crucially, 'the weight of evidence approach requires use of scientific judgement',[98] which seems to imply a modicum of subjectivity and, consequently, value judgements as to, for instance, the right balance between the precautionary and evidence-based approaches. Appraising the interrelationship of different pieces of evidence, having a varying probative value, and their overall effect on the conclusion reached by the EU administration seems highly complex. It involves considerable uncertainty and both technical and political discretion.

[94]Art 57(f) REACH.

[95]Case T-207/18 *Plastics Europe v ECHA* ECLI:EU:T:2020:623, para 63.

[96]Ibid., para 64.

[97]Ibid., paras 66–70 and 96ff.

[98]According to the information provided by the ECHA on its website: https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/weight-of-evidence. See also, S Haack, 'Proving Causation: The Weight of Combined Evidence' in id, *Evidence Matters: Science, Proof and Truth in the Law* (Cambridge University Press 2014), 208.

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Interestingly, the applicant argued on appeal that the intensity of judicial review by the General Court had been insufficient and that the Court had imposed on the applicant an 'unacceptable and unachievable standard of proof' in demonstrating errors, first, in the assessment of individual studies and, second, in these errors' impact on the overall weight-of-evidence analysis. In this applicant's view, the General Court allowed ECHA to make an arbitrary choice of scientific studies. In other words, the appellant seemed to expect the General Court to form an independent view on the correct or at least plausible outcome of the weight-of-evidence exercise. Could the General Court be realistically expected to perform such an intellectual operation? Even if it had appointed expert witnesses, how would it have assessed subsequent allegations against these experts' opinions? How could such court-appointed experts match the authority of dozens of experts involved in the decision-making of the ECHA and of the Commission? Ultimately, the Court of Justice did not find errors in the General Court's overall approach or any obvious distortions of evidence.[99]

This is *not* to say that the General Court's reasoning in this case was flawed or that the outcome was incorrect. The Court might have been perfectly right. Nor is the point that the Court could have done more. The significance of institutional conditions and ensuing limitations has already been explained. In fact, in this and other similar cases, it is not entirely clear whether the court acts as a 'super expert' or only reviews the internal consistency of the contested specialist reasoning. However, the institutional context and some characteristic formulations[100] may suggest that the latter is the case. Generalist adjudication might have reached its innate limits in this regard. Similar judicial strategies may remain the only choice of adjudicators operating in adversarial frameworks when the applicants do not present a lucid, accessible, and compelling account of why and how the contested specialist analysis has been distorted. However, an assessment that seems intelligible, internally consistent, and ultimately plausible to a layperson not sufficiently familiar with limits and criticism of commonly accepted specialist practices, alternative methodologies, and other vital nuances may be assessed differently by a specialist who has acquired large amounts of tacit knowledge and mastered the scientific 'refinements' of everyday and common-sense inquiry. Moreover, the said judicial techniques may imply concealed deference to specialist administration, expected to satisfy only the standard of internal consistency rather than substantive accuracy. After all, they may not directly address the crux of the issue, namely the probative value of evidence or the soundness of scientific reasoning. However, they may create an impression of thorough review by generating long paragraphs of judicial text, appearing at least as intricate as the specialist reasoning subject to review.

In another recent case concerning a magnetic resonance imaging contrast agent product, the European Medicines Agency (EMA) scientific committees found that scientific studies had shown that a substance used in this and other contrast agents, gadolinium, accumulates in the human brain. The long-term clinical consequences of such accumulation remained unknown as the long-term safety data was limited. Adverse neurological effects could not have been ruled out at that stage, although no such effects had yet been demonstrated. Despite disagreements within and between committees, it was considered that the risk-benefit balance of the product in question was

[99]Case C-119/21 P *Plastics Europe v ECHA* ECLI:EU:C:2023:180, in particular paras. 40-55. See also a recent case in which the General Court seems to have largely applied 'consistency' review to address allegations against the 'read-across' (a method under which the properties of certain substances may be predicted from existing data relating to other structurally similar substances) and 'weight-of-evidence' analysis by EFSA, by stressing that the issues have been considered by EFSA rather than directly expressing its own view on the reliability of EFSA analysis, Case T-77/20 *Ascenza Agro et al. v Commission*, paras 452–61, 468–74, 487–513, and 551–86. However, some propositions could be understood as leaning towards the latter (see, paragraphs 562–3 and 575–80). In any case, while reading judicial propositions about complex and uncertain empirical assessments one must keep in mind the institutional context in which they have been produced.

[100]Case T-207/18 *Plastics Europe v ECHA* (n 98), para 207 ('ECHA began with a hypothesis that appears to be at least plausible from a scientific perspective …), para 223 ('In the light of those uncertainties – which are, at the very least, plausible – ECHA took a cautious approach to the question of …').

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no longer favourable.[101] The Commission suspended the market authorisation for gadolinium-containing contrast agents, including the product in question. According to the applicable legal framework,[102] the market authorisations of medicinal products could be suspended if, among other things, their risk-benefit balance was no longer favourable. Considering the precautionary principle, the Commission could rely on data not ruling out scientific uncertainty, but its decision should be substantiated by 'new, objective, scientific or medical data'.[103]

In essence, the General Court had to assess whether the finding that gadolinium accumulates in the brain could plausibly make the risk-benefit balance for the product in question unfavourable despite the remaining uncertainty. The applicant contended, among other things, that the EU administration reversed the burden of proof, requiring the applicant to prove with certainty the absence of adverse neurological effects. Addressing this point, the General Court referred to the reasoning presented by the EMA committee, finding it sufficiently plausible. The Court summarised this reasoning, according to which contrast agents such as the product in question were retained in the brain at a 10-fold higher magnitude than other gadolinium-containing agents and remained there for up to 1 year or more. Although no study showed clinical signs of neurotoxicity, the committee considered that the available data was limited and that such clinical signs may be delayed and subtle. Various unknown factors may obstruct their spontaneous reporting. The Court then referred to the committee's consideration of different available studies. Although all were characterised by uncertainty, the Court concluded that the committee 'relied on an assessment of objective scientific or medical data which do not rule out any scientific uncertainty, but which could nevertheless be serious and conclusive evidence' of the accumulation in the brain and potential toxic effects of the substance in question.[104]

Considering again the general institutional context and, in this case, the General Court's reliance on the opinions of the EMA committees, a reader of this judgement might wonder whether the court confirmed the cogency or at least the internal consistency of the committees' reasoning or, in fact, rather deferred to it in a concealed way. Crucially, the General Court relied heavily on the precautionary principle, which did not require 'solid and persuasive evidence' but only 'serious and conclusive evidence', arguably implying deference to the administration.[105]

The judicial review of the internal consistency of scientific opinions leads to distinct challenges in cases where the applicants contest conclusions drawn from the evidence gathered by the EU administration. Ideally, verifying whether such conclusions are substantiated requires in-depth specialist knowledge of the relevant field from the reviewer. A sufficiently specialised reviewer could conceive of alternative interpretations of evidence and assess whether the chosen interpretation is the most plausible compared to other possibilities. Generalists have difficulty doing that.

This challenge may be illustrated by a recent case brought to the EU Courts by three environmental organisations.[106] These organisations challenged the Commission's refusal to review its authorisation of genetically modified soybeans. The crux of the dispute lay in whether the Commission committed a manifest error of assessment in drawing conclusions from the available scientific data. The applicants claimed to have shown 'legitimate and substantive doubts' about the modified soybean's safety, while the legal conditions for the authorisation were that, in particular, the genetically modified food or feed must not have adverse effects on human health,

[101]Case T-783/17 *GE Healthcare v Commission* (n 87), paras 15–16.

[102]Art 116 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311/67.

[103]Case T-783/17 *GE Healthcare v Commission* (n 87), paras 45–9.

[104]Ibid., paras 66–75. Also, it should be noted that the applicant argued that 300 million doses of gadolinium-containing contrast agents had been administered since 1988 and there was still no data concerning the effects of its accumulation in the brain. Ibid., para 85.

[105]Ibid., para 59.

[106]Case T-177/13 *TestBioTech v Commission* ECLI:EU:T:2016:736.

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animal health or the environment.[107] However, the EU Courts held that the applicants must rather show 'serious doubts as to the lawfulness of the authorisation decision', thereby imposing a higher standard of proof on the applicants.[108]

Nonetheless, in the applicants' view, the Commission and the European Food Safety Authority (EFSA) should have further investigated the concerns or found that the modified soybean was not safe.[109] The applicants argued, among other things, that EFSA failed to require the producer to properly investigate the potential effect of specific biotic (e.g. viruses or insects) and abiotic (e.g. temperature) stressors on the modified soybean when sprayed with glyphosate or other maintenance pesticides. Evidence suggested some consequences on food safety based on studies on other cultivations. Moreover, the applicants claimed that EFSA had not required a sufficient toxicity assessment, given concerns from the available literature.[110] EFSA counter-argued that these issues were irrelevant because of the soybean's intended uses. Also, it found statistically significant differences in only 9 out of 334 comparisons between the modified soybean and its natural comparator after applying biotic stressors and no differences when applying abiotic stressors.[111]

The General Court admitted that some of the Commission's reasons were 'very succinct and ... limited to the finding that the scientific publications in question were taken out of context and provided no new information that might change the conclusions on the toxicity assessment of the modified soybean'.[112] Nonetheless, having referred to the Commission's explanations, which seemed sufficiently plausible,[113] the General Court found no manifest error of assessment. On appeal, AG Szpunar confirmed a 'strong presumption of correctness' of the EU administration's scientific appraisals, which was for the applicant for judicial review to rebut.[114] The Court of Justice concurred.[115]

Notably, in this case, the applicants might have effectively expected the EU Courts, again, to express an independent opinion of the soundness of the Commission and EFSA's conclusions drawn from the available data. In the applicants' view, the General Court instead imposed on them an impossible standard of proof,[116] requiring them to show manifest errors in the contested assessments based on new evidence.[117] As noted by Leonelli, this legal controversy boiled down to a divergent evaluation and interpretation of available scientific evidence and the difference of view regarding the appropriate EU level of precaution about genetically modified organisms.[118] The applicants adduced no 'new' scientific evidence but, instead, aimed at indicating the weak points of the Commission's assessment, which might, in their view, make the entire assessment too uncertain to justify the authorisation. However, where many abstruse and intricate issues regarding detailed stages of a complex assessment are raised, a satisfactory review of its plausibility may require specialist knowledge, including tacit knowledge. Hence, the General Court expected the applicants to discharge the burden of proof.

[107]Arts 4(1) and 16(1) of Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, 23.

[108]Case T-177/13 *TestBioTech v Commission* (n 106), paras 67 and 88; AG Szpunar, Case C-82/17 P *TestBioTech v Commission* ECLI:EU:C:2018:837, paras 55–6; Case C-82/15 P *TestBioTech v Commission* ECLI:EU:C:2019:719, para 40.

[109]Case T-177/13 *TestBioTech v Commission* (n 106), para 82.

[110]Ibid., paras 171ff.

[111]Ibid., paras 163–4.

[112]Ibid, para 205.

[113]Ibid., paras 206–7.

[114]AG Szpunar, Case C-82/15 P *TestBioTech v Commission* (n 108), para 52.

[115]Case C-82/15 P *TestBioTech v Commission* (n 108).

[116]Ibid., para 62. See also, Case T-108/17 *Client Earth v Commission* ECLI:EU:T:2019:215, paras 136–7 and 246–9; Case C-458/19 P *Client Earth v Commission* ECLI:EU:C:2021:802, paras 60–7.

[117]Case T-177/13 *TestBioTech v Commission* (n 106), para 224.

[118]G C Leonelli, 'GMO authorisations and the Aarhus Regulation: Paving the way for precautionary GMO governance' 26 (2019) Maastricht Journal of Comparative and European Law 505, 516.

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It should be added that, in general, civil society expresses concerns about the EU administration's specialist assessments, considering that they are often based on the review of internal consistency of studies produced by the interested industry.[119] There are also concerns about the neutrality of the industry's experts.[120] This institutional context partly explains why the pressure on the judicial epistemic capacity to engage with specialist appraisals has been mounting. Moreover, similar concerns have been expressed about structural arrangements at the EU Courts. In brief, due to the restrictive standing criteria, the EU Courts are usually confronted with the evidence produced by the affected industries.[121]

D. Super-experts

Over time, courts facing repeated legal challenges in areas requiring specialist knowledge may feel sufficiently confident to form independent assessments of the probative value of scientific evidence and the soundness of specialist reasoning.[122] This does not necessarily mean that such judicial review ensures a better protection from arbitrariness. Quite the opposite, it led Vos to express concerns about whether generalist judges should assume the role of 'super experts'.[123] In some cases, the General Court seems confident enough to provide its independent assessment of scientific evidence and reasoning,[124] occasionally finding even 'manifest errors of assessment'.

[119]The system for obtaining data from the applicants formed the basis of one of the allegations of the national court in Case C-616/17 *Blaise and Others*. In response, the ECJ stressed the duty of the EU institutions and bodies to consider the most reliable scientific data, including international research, and not to give the preponderant weight to the industrial studies. This reasoning was criticised as downplaying the difficulties stemming from the differences between standardised 'regulatory science' and more innovative 'research science', the latter leading to more uncertainty that cannot be ignored. S Röttger-Wirtz, 'Case C-616/17 *Blaise and Others*: The precautionary principle and its role in judicial review – Glyphosate and the regulatory framework for pesticides' 27 (2020) Maastricht Journal of European and Comparative Law 529, 540. On the difference between 'peer review' and 'systemic review' in this context see also, A de Boer, 'Scientific assessments in European food law: Making it future-proof' 108 (2019) *Regulatory Toxicology and Pharmacology* 104437 at 4 and the literature cited. See also, C 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.

[120]See among many, L Leone, 'EFSA under Revision: Transparency and Sustainability in the Food Chain' 39 (2020) Yearbook of European Law 536; M Morvillo, 'Glyphosate Effect: Has the Glyphosate Controversy Affected the EU's Regulatory Epistemology?' 11 (2020) European Journal of Risk Regulation 422; G C Leonelli, 'The Glyphosate Saga and the Fading Democratic Legitimacy of European Union Risk Regulation' 25 (2018) Maastricht Journal of European and Comparative Law 582. See also, L B McHenry, 'The Monsanto Papers: Poisoning the scientific well' 29 (2018) International Journal of Risk & Safety in Medicine 193.

[121]Morvillo and Weimer (n 20).

[122]However, the EU Courts may also refuse to delve into empirical issues. See, Case T-783/17 *GE Healthcare v Commission* (n 87), paras 66ff, 98–9. In that case, however, the scientific issue at stake might not have been deemed central to the outcome of the case.

[123]Vos (n 18).

[124]Some of such judicial assessments may appear as requiring less specialist knowledge than others. For instance, in Case T-584/13 *BASF Agro v Commission* (n 67), paras 130–6, the EGC seems to have formed an independent view on the probative value of monitoring data regarding the effects of pesticides on bees which did not indicate causality. In Case T-400/17 *Deza v Commission* ECLI:EU:T:2018:712, paras 70–88; the EGC's reasoning may be interpreted as expressing an independent view on the probative value of scientific studies despite their methodological shortcomings. Since the level of complexity of specific cases and the required expertise differs, one could argue that even someone with a relatively low level of specialist interactional expertise could appreciate the difference between the probative value of studies using, for instance, randomised, placebo-controlled and double-blind pharmaceutical trials and those not complying with these standards, which may be sufficient to solve certain disputes regarding the value of evidence. See, Case T-472/19 *BASF v Commission* (n 88), paras 66–70. Interestingly, in Case T-204/11 *Spain v Commission*, ECLI:EU:T:2015:91 paras 88–93, the EGC formed an opinion on the viability of pollution measurement method chosen by the Commission, having consulted relevant scientific literature. Moreover, in Case T-639/20 *TIB Chemicals v Commission* ECLI:EU:T:2023:374, paras 65–84, 94–109, 127–149, the EGC analysed – without always expressly referring to or summarising the administration's scientific opinions – whether pieces of information provided by a registrant of a chemical substance could be considered a justification for a 'read-across' from information concerning another substance, whether this justification was convincing, and whether the Commission's decision

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Although it is difficult to indicate clear criteria for such 'manifest' errors, these errors may be linked to insufficient justifications of uncertain, potentially controversial, and usually precautionary assumptions.[125] As mentioned, some of such implicit assumptions may seem evident and plausible to experts based on their commonly shared tacit knowledge. Nonetheless, in view of the duty of care, such assumptions may need to be made explicit. Thus, the dividing line between the duty to state reasons and the duty of care becomes blurred, just like the dividing line between the review of manifest errors and the substitution of specialist appraisals becomes blurred, at least to some litigants[126] and commentators.[127]

For instance, a recent case concerned the classification of titanium dioxide as carcinogenic, resulting in legal requirements being imposed on its marketers.[128] Titanium dioxide is an industrial substance used in white pigments and foodstuffs. Manufacturers, importers, downstream users, and suppliers of titanium dioxide challenged a scientific study that formed the basis of ECHA's assessment, alleging a manifest error of assessment. In essence, they put in question the methodology of that study, conducted on rats, arguing that the lungs of the animals had been excessively overloaded with the substance, yielding incorrect results. The applicants contended that the relevant particles agglomerate, resulting in lower density, and that if the ECHA had drawn correct conclusions from previous studies, it would have concluded that the main study was methodologically unreliable.[129] The Commission counter-argued that the applicants expect the court to substitute its own opinion on the correct scientific conclusions to be drawn from this and other studies for that of the ECHA, which would go beyond the confines of judicial review.[130] Moreover, the Commission argued that, faced with incomplete data, ECHA seems to have made some precautionary assumptions about the standard density of the substance and explained in detail additional factors that it considered.[131]

The General Court assessed the probative value of the study by referring to reservations of the French competent authority. It found that the agglomeration of particles resulting in lower density – a phenomenon the parties did not contest – was a relevant factor that the ECHA and the Commission had not sufficiently considered, thereby committing a manifest error of assessment.[132] Crucially, the General Court insisted that its standard of review was not triggered by a substantive disagreement with the scientific conclusions but rather consisted in a procedural check of 'all relevant factors'.[133] However, France appealed this judgement, arguing that the General Court distorted the study in question and substituted its own assessment for that of the

to infer the characteristics of the substance from data on yet another substance was convincing. This task involved an in-depth analysis of scientific studies and arguments, but the EGC could also rely on some inconsistencies in the applicant's submissions.

[125]See, Joined Cases T-279/20, T-288/20 and T-283/20 *CWS Powder Coatings v Commission* ECLI:EU:T:2022:725, para 100. In this case, the EGC scrabbled around the methodological choices of an EU scientific committee and found that in making uncertain assumptions, this committee disregarded relevant though intricate factors – whose meaning and importance was far from immediately clear to an untrained mind – that could change the final conclusions regarding the carcinogenicity of a substance.

[126]In Case C-389/19 P *Commission v Sweden* ECLI:EU:C:2021:131, paras 48–59, the Commission argued before the ECJ that the EGC effectively substituted the Commission's discretionary appraisals with its own in Case T-837/16 *Sweden v Commission*. The ECJ disagreed with the Commission and considered that the EGC simply exercised its power to assess the evidence before it; factual points not being subject to appellate review before the ECJ.

[127]Leonelli (n 19).

[128]Under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, OJ L 353/1, 31.12.2008 (CLP Regulation).

[129]Joined Cases T-279/20, T-288/20 and T-283/20 *CWS Powder Coatings and Others v Commission*, paras 51–3.

[130]Ibid., para 54.

[131]Ibid., paras 55–60.

[132]Ibid., paras 73, 94–5, 97–8, 100–3.

[133]The General Court upheld also another plea related to the misinterpretation of 'intrinsic properties' of the substance, which will not be discussed here.

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competent administration, thereby exceeding the limits of judicial review. The appeal is currently pending.[134]

How to understand the boundary between considering 'all relevant factors' and making or changing the substantive assessment? That a factor is 'relevant' to a conclusion means that it affects the degree in which this conclusion is supported by all the factors (evidence) overall.[135] Therefore, assessing relevance is not purely 'procedural' as it cannot be dissociated from assessing the 'substantive' value of a factor or a piece of evidence in the overall specialist assessment. Performing the test of 'all relevant factors' may require specialist knowledge. Hence, without making any assumptions as to where the truth lay in the case of titanium dioxide, one should be in any case aware that skilled litigators could possibly succeed in convincing generalist judges that the administration has committed a scientific error, overlooking a relevant factor, where grounds for finding such an error could appear contestable to experts possessing specialist tacit knowledge.

Recently, another case presented a disagreement over a choice between two methodological frameworks for assessing the aquatoxicity of a particular composite type of tar.[136] The method chosen by the EU administration, the 'summation method', disregarded a specific factor, namely, the low solubility of the substance as a whole. Instead, this method consisted of assessing the substance's components, resulting in the overestimation of risk to the natural environment. The alternative method advanced by the applicants, the 'water accommodated fraction approach' would consider the low solubility of the substance as a whole, but it would lead to the underestimation of risk.[137]

In its relatively brief analysis, the General Court noted that the EU administration did not provide any reasoning demonstrating that it had taken the low solubility into account. The EU administration's defence strategy relied on arguing that the applicable EU legislation did not allow this factor to be considered. The General Court swiftly dismissed this argument, holding that the administration must consider all relevant factors, an approach endorsed by the Court of Justice. Leonelli questioned whether the 'missing' factor could have been really considered, from the scientific point of view, without determining how exactly the risk would be assessed.[138] In other words, the common-sense logic of requiring the administration to consider 'all relevant factors' might have been unreliable. A decision to include or disregard a specific factor in the analysis could be underpinned by an implicit specialist assessment considering limitations of available methodological approaches. Therefore, for Leonelli, this case exemplified 'quasi-substantive review'. In fact, she suggested that the EU administration's defence strategy might have misled the EU Courts. Hence, she argued that the administration should have rather openly acknowledged and defended its political and technical discretion to choose the more precautionary approach, and consequently choose a specific methodological framework disregarding certain factors, in line with the precautionary principle.[139]

If this criticism concerning the inexistence of a middle ground between the two methodological approaches was valid, something which cannot be decided here (as doing so would require

[134]Case C-71/23 P *France v CWS Powder Coatings and Others*.

[135]Haack, 'Evidence matters . . . ', (n 46) 61: 'a piece of evidence is relevant to a conclusion iff it affects the degree of supportiveness of the evidence overall; ie. iff additing it either contributes to or detracts from the explanatory integration of evidence-plus-conclusion . . . '.

[136]Case T-689/13 *Bilbaina v Commission* ECLI:EU:T:2015:767, and Case C-691/15 P *Bilbaina v Commission* ECLI:EU:C:2017:882.

[137]See the detailed and lucid analysis by Leonelli (n 19).

[138]However, in a follow-up case concerning damages, the General Court interpreted the case in question in following terms: 'those judgements held that there was a manifest error of assessment in that the Commission, when applying the summation method, failed to take into account the low solubility of the mixture itself, that is to say, a factor that can affect the aquatic hazard of the mixture.' According to this interpretation it was feasible to apply the summation method *and* take the missing factor into account. Case T-645/18 *Bilbaína v Commission* ECLI:EU:T:2020:629, para 68.

[139]Leonelli (n 19).

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specialist knowledge), one could take this case as a potential example of the epistemic limits of generalist judges in handling complex and uncertain appraisals, even following the logic of the process-oriented review of 'all relevant factors' and the like. One could also wonder to what extent a flawed defence strategy presented in an essentially adversarial procedural setting before generalist judges may obfuscate the nature of scientific choices and their nuanced connection to value judgements, with unexpected consequences for the final ruling. The absence of specialist tacit knowledge may lead to either overly deferential or inadvertently intense scrutiny. Hence, specialist knowledge may also be necessary for adjudicators to recognise where (informed) deference should be applied to avoid further risks of epistemic trespassing and, consequently, (judicial) arbitrariness.

5. The upper limits of administrative review

A. Institutional and legal contexts

By incorporating a degree of specialist knowledge, administrative review by the boards of appeals was supposed to provide more thorough scrutiny of complex agency decisions while keeping the bulk of complex cases out of the EU Courts' docket.[140] This is why appeals to the BoAs are mandatory before lodging an action to the EU Courts. In case of a subsequent court action, the General Court examines the BoA decision as formally setting out the agency's final position.[141] Appeals can be lodged against the agency's decisions listed in the founding regulations.[142] The founding regulations also decide whether the BoA can only annul (like the EU Courts) or also modify the contested decision. Most BoAs act on an *ad hoc* basis as the relatively low number of appeals does not warrant a permanent structure. The *ad hoc* character may constitute an obstacle to accumulating specialist knowledge and hammering out a thorough standard of administrative review.[143]

Among the BoAs, ECHA BoA faces the most cutting-edge scientific appraisals. Formally, it can modify the contested decisions,[144] but it does not do so, in principle. Additional investigations from the ECHA are usually required following the annulment of contested decisions. The ECHA BOA's output is significant (dozens of final decisions regarding the merits of appeals in 2006–2022). It also functions as a permanent body, although it relies on the assistance of alternate *ad hoc* members. Its adjudicatory panel comprises three members only, including one technically qualified member.[145]

Three elements of the institutional structure of the BoAs, and in particular the ECHA BoA, are relevant. First, thanks to its mixed composition, proximity of the agency, expert resources, and specialisation in a single policy area, the BoAs may be expected to possess a certain degree of interactional specialist knowledge or develop scientific connoisseurship. Therefore, its own empirical appraisals may be informed by specialist tacit knowledge.

[140]For a comprehensive review of legal frameworks governing the different BoAs, see L de Lucia and P Chirulli, *Non-judicial Remedies and EU Administration: Protection of Rights versus Preservation of Autonomy* (Routledge 2021).

[141]See for instance, Case T-102/13 *Heli-Flight v EASA*, ECLI:EU:T:2014:1064, paras 22–32.

[142]See for instance, Art. 91(1) REACH. The founding regulations decide also whether an appeal for failure to act or damages is also available before the BoA. This is *not* the case before ECHA BoA. Moreover, unlike the EU Courts under Art. 277 TFEU, the BoAs cannot examine incidental objections of illegality against higher-order acts, such as their founding regulation or other applicable acts of general application. See, ECHA BoA, Case A-015-2015 *Evonik Degussa*, paras 66 and 70; Case A-006-2017 *Climax Molybdenum*, paras 122–3.

[143]Recently, the Court of Justice criticised the BoA of the European Agency for Energy Regulators for insufficient intensity of review. Case C-46/21 P *ACER v Aquind* ECLI:E:C:2023:182, paras 26–30.

[144]Art 93(3) REACH.

[145]For a complete overview of the institutional and procedures structure of the BoAs (which is rather complex as every BoA functions according to a somewhat different legislative framework) see, Krajewski (n 22), 104–17.

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Second, just like in the case of the EU Courts, the reasoning of the BoAs and the intensity of administrative review are conditioned mainly by the arguments and evidence (and their elucidation), as provided by the parties.[146] However, the procedural practice of the BoAs may be less formalistic. During oral hearings, the ECHA BoA allows for more direct interactions with and between the parties, represented by lawyers and scientific experts alike.[147] In such a procedural context, one can expect a more intense transfer and absorption of specialist knowledge by the adjudicators.

Third, the ECHA BoA does not, however, engage in independent fact-finding (such as commissioning expert opinions) so as not to replicate the agency's decision-making process and not to prolong the proceedings. Nonetheless, the institutional setting makes it somewhat more likely for this BoA to autonomously assess the probative value of scientific evidence and the soundness of specialist reasoning presented by ECHA. And yet, this setting does not warrant that the ECHA BoA will always be able to make a 'better' scientific assessment than dozens of specialists participating in the ECHA decision-making.

The legal framework that the ECHA BoA is confronted with, particularly REACH, is replete with under-determined concepts requiring reaching out to specialist knowledge such as 'risks to human health and the environment' or an 'adequate control' of the risk. This legal under-determinacy and the limited steering capacity of law constituted a challenge for a partly specialised body, such as the ECHA BoA, just like for the generalist EU Courts. In practice, the ECHA BoA acts as the guardian of the non-arbitrariness of the precautionary principle, which also plays an essential role in its reasoning.[148] Responding to appeals brought by the chemical industry, the BoA verifies whether the ECHA had sufficient grounds to identify an issue of concern to public health or the environment and adopt administrative measures.

B. Judging the quality of science

Like in the case of the EU Courts, the intensity of review in specific cases before the ECHA BoA depends on the pleas in law raised, arguments advanced, and the evidence adduced by the appellants. To solve certain disputes, the ECHA BoA can avail itself of standard adjudicatory techniques. It may ascertain the parts of empirical assertions that the appellants have not contested and verify the conclusions drawn from these assertions.[149] It may simply clarify the meaning of the contested decision to the appellants.[150] In some cases, the appellants seem unable to elucidate and substantiate sufficiently their arguments against the ECHA's position. In such cases, the ECHA BoA recalls that the burden of proof and persuasion rests on the shoulders of appellants.[151]

The ECHA BoA has transplanted the case law regarding process-oriented review. Consequently, it verifies the accuracy, reliability, consistency, and comprehensiveness of relevant evidence, which should be capable of substantiating the conclusions drawn from it.[152] The General Court recently clarified that the ECHA BoA should be able to identify 'errors' in the ECHA's appraisals, but it should not be expected to conduct *de novo* review.[153] Notably, the General Court

[146]ECHA BoA, Case A-007-2021 *Global Products Compliance*, paras 34–41.

[147]Krajewski (n 22), 129–35.

[148]ECHA BoA, Joined Cases A-003-2018 to A-005-2018 *BASF SE and Kemira Oyj v ECHA*, paras 85–8.

[149]For instance, ECHA BoA, Case A-018-2014 *BASF Grenzach v ECHA*, para 44; Case A-026-2015 *Envigo Consulting and DJChem Chemicals Poland v ECHA*, para 45–50.

[150]For instance, ECHA BoA, Case A-008-2017 *SI Group UK and Osiris Chemicals*, paras 86–96 and 104–12.

[151]For instance, ECHA BoA, Case A-011-2018 *Clariant Plastics & Coatings v ECHA*, paras 109–28; Joined Cases A-016-2019 to A-029-2019 *Lubrizol France and others*, paras 103-108; Case A-008-2020 *Sustainability Support Service (Europe)*, paras 54-55; Case A-007-2021 *Global Product Compliance (Europe),* paras 39–40.

[152]ECHA BoA, Case A-005-2011 *Honeywell*, paras 76-77; Case A-006-2017 *Climax Molybdenum*, para 38.

[153]Case T-125/17 *BASF v Commission* (n 23), para 65. A Volpato and M Chamon, 'Sketching Out the Role and Function of the ECHA Board of Appeal: Germany v ECHA and BASF v ECHA' 45 (2020) European Law Review 840.

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distinguished 'manifest errors of assessment' from ordinary 'errors'. The Court can annul EU legal acts based on the former, whereas the ECHA BoA can also annul or modify the ECHA decisions based on the latter. This distinction implies a more intense standard of administrative review than judicial review. However, which errors are 'manifest' to adjudicators mainly depends on the lucidity and strength of argumentation presented by the litigants. Therefore, indicating criteria to differentiate manifest from ordinary errors seems challenging.

Notably, the ECHA BoA's reasoning suggests that it does not shy away from expressing its own view on the probative value of scientific evidence (usually, scientific articles reporting on chemical studies),[154] the reliability of specific studies or tools and conclusions drawn from the available data[155] while considering technical limitations of particular methodologies.[156] As the ECHA BoA put it, 'in conducting its administrative review of Agency decisions, the Board of Appeal possesses certain technical and scientific expertise which allows it to enter further into the technical assessment made by the Agency than would be possible by the European Union Courts.'[157] In other words, considering its institutional setting, the ECHA BoA may benefit from its independent specialist tacit knowledge rather than only explicit knowledge provided mainly in a written form by the parties.

A review of recent decisions suggests that the ECHA BoA indeed evaluates independently the probative value of scientific evidence and the soundness of specialist reasoning underpinning the ECHA's decisions to request further information from the registrants on substances raising concerns.[158] For instance, in a recent case, the BoA assessed the value of a predictive model concerning the persistence of metabolites of an antioxidant in rubber mixtures used to produce tyres. The appellants argued that ECHA had been wrong to require further tests, having considered that the substance posed an environmental hazard. The model used by the appellant, although confirming that the substance itself was persistent, predicted that its metabolites were less so. The BoA found the model to constitute 'a deductive chain' in which 'the identity of the metabolites can be predicted, their polarity deduced from their identity, and their persistence from their polarity.' The BoA considered the conclusions drawn from this model as too uncertain unless corroborated with further data.[159]

However, the BoA was at the same time of the view that the specific study requested by the ECHA concerning the metabolites would be hindered by the substance's low solubility. It relied on OECD guidelines and a scientific report criticising that study. It concluded that the ECHA could not oblige the appellants to achieve specific results but only to make reasonable efforts to identify the metabolites.[160] Interestingly, Germany challenged the latter BoA decision before the General Court, seeing this instance of administrative review as too intense. It argued that the test chosen by the ECHA was state-of-art at that time. However, the General Court did not find an error in the applied standard of review and the BoA's assessment.[161]

[154]For instance, ECHA BoA, Case A-015-2015 *Evonik Degussa v ECHA*, paras 161-169 and 175-186; Case A-009-2014 *Albemarle Europe*, paras 100-102 (although in this case the agency itself seems to have admitted some concerns about the scientific publication on which it relied); Case A-004-2017 *3v Sigma v ECHA*, paras 68-70.

[155]For instance, ECHA BoA, Case A-006-2017 *Climax Molybdenum*, paras 54-85; Case A-005-2016 *Cheminova*, paras 95–6; Joined Cases A-003-2018 to A-005-2018 *BASF SE and Kemira Oyj v ECHA*, paras 111–24; Case A-001-2019 *Solvay Fluor v ECHA*, paras 139–54.

[156]See, Case A-026-2015 *Envigo Consulting and DJChem Chemicals Poland v ECHA*, paras 67–73; Case A-008-2018 *Taminco BVBA and Performance Additives Italy v ECHA*, paras 73–84.

[157]A-005-2014 *Akzo Nobel Industrial Chemicals et al.*, para 54.

[158]See specific legal conditions that ECHA needs to satisfy, Ibid., paras 59-60. For instance, see a recent decision in which the ECHA compared the probative value of two scientific tests favoured by the appellant and the ECHA, Case A-002-2021 *Lanxess and Schirm*, paras 94–104.

[159]Case A-026-2015 *Envigo* Consulting, para 52–60.

[160]Ibid., paras 118–25 and 133–42. See also a case in which the adequate temperature to conduct the study was disputed, Case A-004-2017 *3v Sigma v ECHA*, paras 88–95.

[161]Case T-755/17 *Germany v ECHA* ECLI:EU:T:219:647.

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The BoA may also scrutinise the probative value of competing scientific evidence. In a case concerning the evaluation of certain aluminium salts, the appellants questioned the ECHA's assessment that there was a genotoxicity concern to be clarified. The appellants alleged, among other things, that the ECHA requested further information on genotoxicity based on unreliable *in vivo* and *in vitro* studies. In contrast, it disregarded the appellants' high-quality *in vitro* studies showing no genotoxicity. The BoA assessed the appellants' studies as more reliable, noting that studies relied on by the ECHA had deficiencies in reporting and deviations from the OECD guidelines. The ECHA had acknowledged these deficiencies but had not drawn appropriate conclusions.[162]

C. Informed and overt deference

Specialist knowledge may help adjudicators to decide when and how to apply deference that is likely to be 'informed'. As mentioned, deference should also be 'overt' to allow the audience to understand the degree and reasons for it. For instance, in one of the cases before the ECHA BoA, the parties used different calculation methods and categories to assess a change in maternal body weight after exposure to the investigated substance and, thus, the severity of this substance's maternal toxicity. In the absence of legislative guidance, the BoA considered as sufficiently authoritative a categorisation assumed in a study relied on by the appellants themselves, and it upheld the ECHA decision. However, it noted that even the relevant annex to the CLP Regulation[163] acknowledged that this was 'a complex issue because of uncertainties surrounding the relationship between maternal and developmental toxicity'.[164] Although the ECHA BoA noted that ECHA did not fully explained how it arrived at its conclusions, it did not find these conclusions unreasonable. Openly acknowledging and justifying the deference arguably helps maintain public trust in the ability of adjudication to remain vigilant and rule out the risk of arbitrariness.

Crucially, the ECHA BoA sometimes invokes the concept of a 'scientific disagreement' or a 'difference of scientific opinion' between the parties. Such scientific disagreements are insufficient to find that the ECHA has committed an error of assessment.[165] The purpose of this concept is not entirely clear, but it seems to emphasise the relatively high threshold of proof and persuasion imposed on the appellants. It also seems to justify a degree of the BoA's deference to the ECHA in cases where scientific assessments remain uncertain. The adjective 'scientific' is often but incorrectly used as a synonym of 'reliable'.[166] Therefore, it may be interpreted as marking cases in which the BoA chooses to defer to the ECHA without denying the uncertainty of the ECHA assessment and, at the same time, the reasonability of appellant's scientific counter-arguments. The BoA explained in this regard that 'the data available for substance evaluations is in some cases inconsistent or indeed contradictory and in other leave questions open. It is therefore not surprising that there is often a difference of opinion between experts when assessing the available data'.[167] As a 'scientific disagreement' or 'difference of scientific opinion' implies that the arguments of both parties are reasonable, from the scientific point of view, the BoA seems to implicitly confirm that the ECHA's assessment, although uncertain, is not arbitrary. This kind of 'informed' deference arguably implies a substantive check on the exercise of discretion by the

[162]Joined Cases A-003-2018 to A-005-2018 *BASF SE and Kemira Oyj v ECHA*, paras 103–10. Moreover, the BoA considered that the ECHA had not adequately explained how the requested information could lead to better risk management measures. Ibid., paras 133–4.

[163]CLP Regulation (n 126).

[164]ECHA BoA, Case A-023-2015 *Akzo Novel Chemicals ea*, paras 67–8 and 74–6.

[165]ECHA BoA, Case A-004-2014 *Altair Chimica et al.*, paras 54, 70 and 82; Case A-018-2014 *BASF Grenzach*, paras 134, 155, 164 and 232; Case A-015-2019 *Polynt*, paras 70–3.

[166]S Haack, 'Trial and Error: The Supreme Court's Philosophy of Science' 95 (2005) American Journal of Public Health S66.

[167]ECHA BoA, Case A-015-2015 *Evonik Degussa*, para 174.

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administration. In this sense, informed deference is compatible with the conception of the rule of law as the pursuit of non-arbitrariness. It does not risk leaving the duty of care unenforced.[168]

For instance, the BoA dealt with a case concerning whether tumours caused by a substance, observed in rodents, were due to a receptor specific to these animals and, consequently, whether there was a concern about human health. The BoA began by noting a strong presumption that tumours induced by the substance are relevant to humans, based on the wording of an annex to the CLP Regulation.[169] Substances inducing tumours in well-performed experimental studies on animals are considered human carcinogens unless there is 'strong evidence' that the tumour formation mechanism is irrelevant for humans.[170] Subsequently, the BoA reflected upon the conclusions that could be drawn from the available scientific studies.[171] It also checked these conclusions with other available studies.[172] It noted that the existing evidence did not amount to final proof of whether the receptor at issue, which the humans do not have, was decisive in the formation of tumours by the substance under examination or whether there were also other modes of action. The BoA found here a 'scientific disagreement' and 'diverging scientific opinion' between the parties, not sufficient to demonstrate an error by the ECHA.[173] Ultimately, it relied on the precautionary principle[174] and upheld the ECHA's concern.

Interestingly, the General Court dealt with a similar issue in another case, styling its reasoning in a somewhat different way that suggested the review of 'consistency' of the ECHA opinion. The Court stressed the *prima facie* plausibility of ECHA opinion and the fact that the scientific uncertainty at issue was acknowledged and considered therein. The Court highlighted the applicant's responsibility to adduce evidence making the opinion implausible, but it provided no hints as to whether the applicant's reservations were reasonable or not. Therefore, it was unclear how 'informed' the judicial review in this case was. In fact, the Court might have concealed deference by focusing on the internal consistency of the assessment.[175]

Another somewhat similar case concerned the evaluation of triclosan, a broad-spectrum antibacterial commonly used in hygiene products. The appellant contested ECHA request for further studies because, in its view, the requested enhanced developmental neurotoxicity study would not produce useful information, among other things.[176] The appellant contended that the existing data in rats, in combination with human clinical data, did not warrant further animal testing for neurotoxicity or reproductive toxicity due to considerable evidence that the rat and human thyroid systems differ. The BoA identified here again a difference of scientific opinion.[177] It was satisfied that the ECHA admitted uncertainty, while explaining why the requested state-of-art studies might still produce useful information.[178] The appellant challenged this decision before the General Court alleging an insufficient standard of administrative review. However, the Court found the BoA standard sufficient, even if involving a degree of deference.[179] In brief, the Court seemed satisfied with administrative review implying 'informed' and 'overt' deference.

[168]See also, ECHA BoA, Case A-017-2014 *BASF v Commission*, paras 72–9.
[169]CLP Regulation (n 126).
[170]ECHA BoA, Case A-007-2019 *Chemours v ECHA*, paras 52–4.
[171]Ibid., paras 56–79.
[172]Even though they were submitted by the appellants out of time. Ibid., para 62. See also, para 68.
[173]Ibid., paras 64 and 67.
[174]Ibid., para 76.
[175]Case T-636/19 *Chemours Netherlands v ECHA*, paras 56–7.
[176]Case A-018-2014 *BASF Grenzach*.
[177]Ibid., para 134.
[178]Ibid., paras 161–8 and 169ff.
[179]Case T-125/17 *BASF v ECHA* (n 23).

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6. Beyond adjudication

The analysis performed up until this point has been concerned with the inherent limits to the capacity of generalist or even partly specialist adversarial adjudication to enforce the duty of care in cases raising complex and uncertain empirical issues. It has discussed contemporary science-intense litigation at the EU level and the nature of scientific issues it raises. It has been argued that, ideally, adjudicators would have to possess a degree of specialist knowledge, including tacit knowledge, to maximise the chances of ensuring the non-arbitrariness of scientific appraisals made by the EU administration. Such specialist knowledge would also be necessary even to perform 'just' process-oriented review and to fully act as 'catalysts' of more structured scientific decision-making. The frequently used 'consistency' review seems fallible, as it may conceal deference, which does not mean, however, that courts, operating within specific institutional confines, can be realistically expected to do more than that.

There are institutional limits to reforms aimed at introducing at least partly specialised and consequently more intense adjudication at the EU level. When it comes to the General Court, the main obstacles are the system of judicial appointments and the extent to which specialisation may undermine the uniformity of the case law. When it comes to the BoAs, further reinforcing their composition and specialisation would require more resources. Currently, most BoAs function on an *ad hoc* basis, making the accumulation of knowledge a real challenge. The relatively low or uncertain number of appeals may not warrant permanent structures. Moreover, there is always a risk of such bodies taking over the responsibility for primary decision-making. Nonetheless, the BoAs seem promising instruments for reducing the risk of arbitrariness in the fields where relatively stable and coherent litigation concerning complex and uncertain specialist assessments may be expected.[180] However, the setting up of a partly specialist BoA is not sufficient, in and of itself, to secure thorough review and, occasionally, informed and overt deference only. The intensity of administrative review depends on the specific resources assigned to the BoA, including a sufficiently broad composition ensuring the necessary expertise.

Undoubtedly, attributing adjudicators with inquisitorial mandates exacerbate the risk of them taking over the primary responsibility for decision-making and generating additional costs. However, still largely adversarial but more flexible procedural frameworks might help reduce the risk of tolerating arbitrariness in policy fields in which litigants are not likely to afford sufficiently specialised and experienced representation. For instance, where non-profit environmental organisations litigate in the public interest, one may have doubts if deficiencies in their litigation strategies, procedural mistakes, or simply inability – due to their limited resources – to produce fully compelling scientific evidence corroborating reasonable doubts should be treated with the same procedural rigour as procedural errors committed by resourceful economic operators or EU bodies.[181] Procedural rules could leave to the adjudicators flexibility to address *de facto* inequalities between the parties, including by engaging in additional fact-finding where the weaker party raises sufficiently reasonable doubts rather than fully rebutting the presumption of correctness afforded to EU administration. Moreover, suppose a flexible procedural framework and practice were

[180]The BoAs with binding powers cannot be introduced within the EU institutions, as their autonomy is safeguarded by the EU Treaties. However, it is possible to introduce similar bodies, not equipped with binding powers, and oblige the institutions to reply to these bodies' recommendations. Even if rejected, such recommendations can subsequently facilitate judicial review to a considerable extent. For an example see, C Brescia Morra, R Smits and A Magliari, 'The Administrative Board of Review of the European Central Bank: Experience After 2 Years' 18 (2017) 18 European Business Organization Law Review 567.

[181]See a commentary to Joined Cases Case T-371/20 and T-554/20 *Pollinis France v Commission* ECLI:EU:T:2022:556, 'Commission appeals General Court's judgement concerning access to documents relating to the 2013 guidance document on bees', pointing out how the General Court treated procedural submissions of the parties, available at: https://eulawlive.com/commission-appeals-general-courts-judgment-concerning-access-to-documents-relating-to-the-2013-guidance-document-on-bees/# ('the ruling seems to involve a mild rebuke of the Commission that should not use its procedural expertise to win at the cost of the applicants . . . '). See also, ECHA BoA, Case A-004-2014 *Altair Chimica et al*, paras 23-24, in which BoA provided the appellant with an opportunity to clarify its pleas in law.

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combined with a specialisation of adjudicators, including a training of adjudicators in scientific matters. Such adjudicators might decide with greater certainty when commissioning additional expert opinions would be justified. They could also rule on subsequent substantive allegations against the expert opinions.

Nonetheless, there is still a limit to the ability of adjudication to ensure the non-arbitrariness of complex and uncertain specialist assessments. When it comes to vast and internally diversified fields, such as the risk regulation of chemicals, pharmaceuticals, foodstuffs, or AI systems, it is unlikely that a limited group of adjudicators, even specialised ones and equipped with fact-finding powers, would be able to match the epistemic assets of several dozens of experts involved in the primary decision-making within the EU agencies and institutions. Adjudication, as a means of ensuring non-arbitrariness through the settlement of legal disputes by neutral adjudicators, can indeed reduce the risk of arbitrariness, but it is essential to be realistic about its inherent limitations.

This is why more scholarly attention is still needed to understand the risks of arbitrariness occurring at the ground level, within EU regulatory or administrative processes, and conceive means to address these risks where they occur, in a systemic and *ex ante* way, rather than only *ex post* in a court or in a BoA. It is necessary to regularly examine the applicable standards and practices of experts and specialised administrators involved in primary decision-making within the EU administration, including especially those relating to transparency, inclusivity, and accountability.

For instance, the development and constant revision of robust conflict-of-interest policies proves to be essential, as follows from the finding of extra-judicial accountability bodies such as the European Ombudsman[182] and the European Court of Auditors[183]. Crucial is also enhancing the transparency of decision-making involving complex and uncertain science. As follows from recent judgements of the EU Courts[184] and recommendations of the European Ombudsman,[185] there is still space for much improvement on the side of the EU institutions and bodies. The broader goal is to allow EU citizens and specialised civil society to closely monitor and influence 'in real time' EU decision-making, thus reducing the potential for arbitrary decisions.

Where all the relevant information is made proactively available (transparency), where the input of stakeholders is genuinely considered (inclusivity), and where the authority engages with and responds to this input, occasionally reconsidering its initial position (accountability), the risk of arbitrariness is reduced. Mechanisms capable of intervening to address systemic issues concerning transparency, inclusiveness, and accountability in response to individual complaints or systemic issues, such as the European Ombudsman, have a much more significant role to play in upholding the rule of law as the pursuit of non-arbitrariness than hitherto acknowledged in EU legal studies, given at least the number of publications focusing on the EU Courts and those concerning other mechanisms.

[182]For instance, Decision on how the European Commission involved stakeholders and managed conflicts of interest in reviewing the protection goals for assessing environmental risks of pesticides (case 1402/2020/TE), available at https://www.ombudsman.europa.eu/en/decision/en/148938. See also, a disagreement between the General Court and the Court of Justice in Case T-594/18 *Pharma Mar v Commission* ECLI:EU:T:2020:512 and Joined Cases C-6/21 P and 16/21 P *Germany v Pharma Mar and Commission* ECLI:EU:C:2023:502.

[183]European Court of Auditors, 'Annual report on EU agencies for the financial year 2021', available at https://www.eca.europa.eu/en/publications?did=62271.

[184]For instance, Case T-371/20 and T-554/20 *Pollinis France v Commission* (n 181, appeal before the Court of Justice pending) regarding the transparency of work on a scientific guidance document by the European Food Safety Authority concerning the risk assessment of the impact of pesticides on bees.

[185]Decision of the European Ombudsman in case 2142/2018/EWM on the European Commission's refusal to grant access to Member State positions on a guidance document concerning the risk assessment of pesticides on bees, https://www.ombudsman.europa.eu/en/decision/en/122313.

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7. Conclusion

This Article has inquired into the epistemic limits of EU judicial and administrative review in handling empirical complexity and uncertainty. It has argued that, in analysing the intensity of review in specific cases, it is necessary to move beyond juristic formulas and concepts, and to consider the institutional context in which judicial and administrative review is performed, as well as the nature of specialist knowledge, which cannot be easily 'conveyed' to and 'absorbed' by generalist adjudicators. The ensuing key question is how likely it is that, in specific cases, the EU adjudicators are able to form an independent and reliable opinion on the probative value of complex and uncertain evidence and on the soundness of the administration's specialist reasoning. In such a way, it is possible to appraise the boundaries within which judicial review, or proliferating administrative review by the partly specialised BoAs, can uphold the rule of law understood as the pursuit of non-arbitrariness.

The Article has contended that, if adjudication was the sole or main mechanism for ensuring the rule of law at the EU level, a degree of specialist knowledge would be necessary for the adjudicators to identify breaches of the duty of care given the nature of empirical issues raised before the EU Courts or BoAs at present. Specialist knowledge may be necessary even to perform process-oriented review. The questions about the process of reasoning and its consistency are not necessarily epistemically 'easier' than direct review of substantive issues. This is why specialised adjudicators should be able to enforce the duty of care by independently assessing the probative value of complex and uncertain evidence and the soundness of specialist reasoning, thereby reducing the risk of arbitrariness in a meaningful way. They may also apply deference, but this deference is more likely to be informed and overt, thereby including a meaningful check on the administration's complex and uncertain empirical assessment. On the contrary, generalist adjudicators may have no choice but to completely defer to the administration's expertise. While trying to at least verify the internal consistency of the administration's reasoning, they may effectively conceal deference.

Nonetheless, there are limits to a further expansion of the epistemic capacity of EU adjudication, due to the institutional structure of the EU Courts and the BoAs. A further pursuit of non-arbitrariness at the EU level may still consist in developing more flexible procedural frameworks and practices thanks to which the adjudicators could address an imbalance of litigation resources between the parties, such as civil society, the industries, and EU institutions and bodies. However, a long-term solution lies in reinforcing administrative means fostering the transparency, inclusivity, and accountability of decision-making at the moment when this decision-making occurs, rather than *ex post*. Mechanisms capable of intervening to address these issues systemically, including in response to individual complaints or systemic issues, such as the European Ombudsman, have a much more significant role to play in upholding the rule of law as non-arbitrariness than hitherto acknowledged in EU legal studies.

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