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THE TRANSPARENCY OF EU AGENCY SCIENCE – TOWARDS A NEW PROACTIVE APPROACH

EÓGAN HICKEY AND MARIA WEIMER*

Abstract

Recent health and environmental crises have emphasized the importance of transparency of agency science, i.e. the scientific information that underpins public regulation. Yet how EU law shapes the transparency of EU agency science and whether it contributes to publicly holding experts to account for the quality of their advice, remains an open question. This article analyses the transparency regimes of three EU agencies. We show that the EU legal approach to transparency of agency science is undergoing significant change, through legislative reform and agency practice. The traditional "passive" approach based on the Access Regulation is fragmented and reveals several shortcomings. Recent trends, such as the 2021 reform of the General Food Law, indicate that the EU is moving towards "proactive transparency", which improves expert accountability. Our study contributes to debates on EU risk regulation and the general reform of the Access Regulation. The article offers an interdisciplinary perspective informed by political epistemology, namely the study of the role of experts in public decision-making.

1. Introduction

Scientific advice in public regulation is a double-edged sword. As the current health and environmental crises demonstrate, no modern regulatory system can achieve its goals without it. At the same time, the problem-solving potential of public regulation critically hinges on the epistemic quality of scientific advice. The dilemma is that such epistemic quality cannot simply be ensured through black-box scientific peer-review processes, although these remain crucial. Instead, it is widely recognized that scientific advisors ought

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to explain and justify expert judgements in public fora.[1] The production and use of agency or regulatory science[2] are deeply intertwined with political and economic purposes, which requires a shift towards new, public forms of expert accountability.[3] Transparency of regulatory science is an important precondition for such expert accountability. Transparency can broadly be defined as "the conduct of [regulation] in a fashion that makes decisions, rules and other information visible from the outside".[4] The visibility of scientific information, which underpins regulatory decisions of high public salience and impact on health and the environment, fulfils several functions.[5] It enables public scrutiny, which in turn helps ensure the epistemic quality (e.g. through inclusion of diverse knowledge; detection of blind spots) of public regulation. It is also a precondition for public participation, as well as trust in regulation.[6]

In this article, we explore how law can help unfold the potential of transparency as a mechanism of expert accountability, broadly conceived, in the field of EU risk regulation. EU law has promoted transparency as a legally protected value built on the high normative aspiration of an open polity operating "as closely as possible to the citizen".[7] There is a constitutional

1. See Holst and Molander, "Public deliberation and the fact of expertise: Making experts accountable", 31 *Social Epistemology* (2017), 235–250; Lentsch and Weingart (Eds.), *The Politics of Scientific Advice: Institutional Design for Quality Assurance* (Cambridge University Press, 2011); Jasanoff, *The Fifth Branch. Science Advisors as Policymakers* (Harvard University Press, 1990); Arcuri, "Three dimensions of accountability for global technocracy" in Arcuri and Coman-Kund (Eds.), *Technocracy and the Law: Accountability, Governance and Expertise* (Routledge, 2021), pp. 62–87; Weimer and de Ruijter (Eds.), *Regulating Risks in the European Union: The Co-production of Expert and Executive Power* (Hart Publishing, 2017).

2. This term, as coined by Sheila Jasanoff, refers to the particular use of scientific advice in public regulation, and should be differentiated from broader notions of research science. See Jasanoff, *Science at the Bar* (Harvard University Press, 1995); and Jasanoff, "Quality control and peer review in advisory science" in Lentsch and Weingart, op. cit. *supra* note 1, pp. 19–35. In this article we use the terms agency science and regulatory science interchangeably.

3. Arcuri and Coman-Kund, op. cit. *supra* note 1.

4. Hood, "Accountability and transparency: Siamese twins, matching parts, awkward couple?", 33 *West European Politics* (2010), 989–1009, at 989. See also Way et al., "Medicines transparency at the European Medicines Agency (EMA) in the new information age: The perspectives of patients", 19 *Journal of Risk Research* (2016), 1185–1215.

5. See an overview in Way et al., ibid.

6. See Hood, op. cit. *supra* note 4; Hood and Heald (Eds.), *Transparency: The Key to Better Governance?* (OUP, 2006); Jasanoff, "Transparency in public science: Purposes, reasons, limits", 69 *Law and Contemporary Problems* (2006), 21–45; Mendes, "The principle of transparency and access to documents in the EU: For what, for whom and of what?", University of Luxembourg Working Paper No. 2020-004; Holst and Molander, "Responding to crises – Worries about expertization" in Riddervold et al. (Eds.), *The Palgrave Handbook of EU Crises* (Palgrave Macmillan, 2021), pp. 647–665; Schmidt and Wood, "Conceptualizing throughput legitimacy: Procedural mechanisms of accountability, transparency, inclusiveness and openness in EU governance", 97 *Public Administration* (2019), 727–740.

7. Art. 10(3) TEU.

commitment to open decision-making in both the Treaty[8] and EU secondary legislation, which extends to EU regulatory science. In the field of risk regulation, EU case law has established transparency as one of the core standards, next to independence and excellence, to which EU regulatory science is held.[9] However, despite the widespread agreement on the normative value of transparency, its actual implementation in EU institutional practice remains controversial and fraught with difficulties. The currently dominant EU legal approach is one of "passive transparency" based on the EU Access Regulation,[10] which entails that EU institutions will only provide access to documents – and hence remain passive hitherto – once an applicant requests disclosure. This approach presupposes that citizens dispose of certain (legal, financial, epistemic) resources. Moreover, granting access requires balancing between the public interest of access and the need for confidentiality to protect competing interests; in the case of risk regulation this concerns above all the commercial interests of the regulated industry and the administrative process respectively.

The traditional approach is coming under increasing pressure today. The Access Regulation is 20 years old and subject to ongoing reform discussions. At a recent event on the future of the Access Regulation, the EU Ombudsman called for this law to be modernized, in order, among other things, to "be aligned more closely with the citizen rights enshrined in the Lisbon Treaty, encourage greater pro-active transparency and take account of important case law concerning transparent decision-making".[11] Scholars have discussed various shortcomings of the current legal regime on access to documents including its legislative norms, their judicial interpretation as well as application by EU institutions.[12] Most criticism has focused on the outdated

8. Art. 10(3) TEU, Art. 11(2) TEU, Art. 15(3) TFEU.

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

10. Regulation (EC) 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, O.J. 2001, L 145/43 (hereafter: Access Regulation).

11. See <www.ombudsman.europa.eu/en/press-release/en/149154> (all websites last visited 23 March 2022).

12. See Alemanno, "Unpacking the principle of openness in EU law: Transparency, participation and democracy", 39 EL Rev. (2014), 72–90; Prechal and De Leeuw, "Dimensions of transparency: The building blocks for a new legal principle?", 1 REALaw (2007), 51–62; Mendes, op. cit. *supra* note 6; Curtin and Leino-Sandberg, "Openness, transparency and the right of access to documents in the EU", Robert Schuman Centre for Advanced Studies Research Paper No. RSCAS 2016/63; Leino-Sandberg, "Transparency, participation, and EU institutional practice: An inquiry into the limits of the 'widest possible'", EUI Dept. of Law Research Paper No. 2014/03; Hofmann and Leino-Sandberg, "An agenda for transparency in the EU", *European Law Blog*, available at <europeanlawblog.eu/2019/10/23/an-agenda-for-transparency-in-the-eu/>.

nature of the current rules[13] and on the way in which the currently applicable regime of exceptions to the right of access strikes a balance between transparency and secrecy.[14] Here, the existence of mandatory exceptions under the Access Regulation and the creation by the ECJ of additional general presumptions of confidentiality – applicable in administrative procedures – has been the subject of particular concern. Moreover, the general Access Regulation often sits uncomfortably with special legislative frameworks created over the years in different areas of EU law.[15] Overall, the mire of rules and exceptions as well as of general and special legal frameworks across different policy fields causes legal fragmentation of the EU fundamental right to access to documents. It also leads to inconsistent application of the EU access rules by different EU institutions and bodies, prompting calls for more harmonized EU transparency standards.[16]

Most of the legal scholarship on transparency has focused on the main EU institutions, especially the Commission and the Council. In contrast, the transparency of information held by EU agencies remains a niche topic.[17] In this article, we seek to further the study of how EU law shapes transparency in the field of risk regulation. While this is an important topic in its own right, our research also contributes to the general reform discussion around the Access Regulation. First, risk regulation illustrates well the problematic nature of the ECJ's distinction between legislative and administrative transparency, whereby the former is seen as privileged, and the latter limited by the creation of general presumptions. Scientific documents are administrative in nature but often serve as the basis for general rules, which affect large groups of people. Second, as we will show, the legal framework for access to documents of EU agencies is strongly fragmented, although recent reforms have achieved some harmonization.

13. Both due to technological developments and changes in the Lisbon Treaty. See e.g. Curtin and Leino-Sandberg, op. cit. *supra* note 12; "Report of the European Ombudsman conference – Access to EU documents: What next?", available at <www.ombudsman.europa.eu/en/event-document/en/149745>.

14. Overview in Curtin and Leino-Sandberg, op. cit. *supra* note 12; Leino-Sandberg, "Disruptive democracy: Keeping EU citizens in a box" in Govaere, Garben and Nemitz (Eds.), *Critical Reflections on Constitutional Democracy in the European Union* (Hart Publishing, 2019), pp. 295–316.

15. On tensions with data protection see the recent Opinion of A.G. Pikamäe in Case C-184/20, *OT* v. V*yriausioji*, EU:C:2021:991; also Korkea-aho and Leino-Sandberg, "Who owns the information held by EU agencies? Weed killers, commercially sensitive information and transparent and participatory governance", 54 CML Rev. (2017), 1059–1091.

16. See Report of the European Ombudsman conference cited *supra* note 13.

17. Although this seems to be changing: see contributions to recent conference organized by Maastricht University, "Transparency and Participation in the Face of Scientific Uncertainty", available at <www.maastrichtuniversity.nl/events/transparency-and-participation-face-scientific-uncertainty-online>.

Third, risk regulation has become a field for experimentation with new approaches to transparency. The COVID-19 pandemic but also the ongoing climate emergency have emphasized the need to rethink access to documents as an empowering tool for environmental citizenship in the light of the EU Green Deal. The integrity of EU regulatory science is of special concern here. Numerous controversies, such as cases of conflict of interests in European agencies,[18] the EU glyphosate reauthorization amidst concerns over industry manipulated studies,[19] the authorization of endocrine disruptors,[20] and the drafting of the EU bee guidance,[21] just to name a few examples, have reignited the debate about the adequacy of existing rules and practices, which aim at securing the quality and integrity of EU regulatory science, with transparency of scientific advice being a central issue in current debates. Sometimes, the above-mentioned controversies have triggered legislative responses, which indicate that the passive approach to transparency based on the exercise of access rights might be outdated, making comprehensive legislative reform of transparency rules for EU agencies ever more urgent. For example, the recently reformed EU General Food Law[22] embraces a new approach of "proactive transparency" for EU risk assessments in the food chain, which no longer depends on access requests. Some EU agencies have embraced this proactive model, while others fail to meet even the minimum standards of the Access Regulation.

This article contributes to existing scholarship by offering a thorough analysis of the current EU legal framework for access to documents of EU agencies, identifying its shortcomings as well as recent trends. Existing

18. See European Court of Auditors, "Management of conflict of interests in selected EU agencies", (2012) special report No. 15, available at <www.eca.europa.eu/Lists/ECADocuments/SR12_15/SR12_15_EN.PDF>.

19. The "Monsanto papers" scandal, which emerged in the context of US litigation against Monsanto, suggested the company's manipulation of the scientific studies underpinning the marketing of the weedkiller glyphosate. For its implications at EU level see <www.euractiv.com/section/agriculture-food/news/eu-agencies-accused-of-cherry-picking-evidence-in-glyphosate-assessment/>; see Arcuri and Hendlin, "The chemical anthropocene: Glyphosate as a case study of pesticide exposures", 30 *King's Law Journal* (2021), 234–253.

20. Conflict over endocrine disruptors has resulted in the European Parliament blocking the identification criteria proposed by the Commission for inadequately addressing health and environmental concerns; see <www.europarl.europa.eu/news/en/press-room/20171002IPR85122/identifying-endocrine-disruptors-meps-block-plans-exempting-some-pesticides>.

21. The implementation of EFSA's 2013 bee guidance has been deadlocked due to disagreement over the scientific risk assessment with the European Parliament rejecting the Commission's proposal in 2019; see <www.politico.eu/article/eu-battle-over-bees-pesticides-heads-for-another-brick-wall/>.

22. Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 Jan. 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, O.J. 2002, L 31/1–24 (General Food Law or GFL).

studies have already begun to map the crucial role of EU agencies as holders of information that is both commercially sensitive and of high public interest for regulators as well as citizens.[23] Scholars have criticized agency practices and interpretation of transparency rules for being in tension with EU public access legislation.[24] However, the emergence of new approaches to transparency in EU legislation and agency practice, which go beyond the traditional approach, has not yet been comprehensively studied.

This paper's scholarly contribution is threefold. First, by capturing new developments, it contributes to a better understanding of the EU legal approach to transparency in the field of risk regulation and agency science. It analyses recent developments, such as the 2021 reform of EU General Food Law as well as new ECJ case law on general presumptions in the field of risk regulation. New light is also shed on the role of the Aarhus Regulation in ensuring transparent risk regulation.

Second, by analysing the tensions between the passive and the proactive approach to transparency, this analysis contributes to the general reform discussion around the Access Regulation. In particular, this study points to the need to improve administrative transparency as a key challenge to be addressed in EU law on access to documents in the years to come.[25]

Finally, the article contributes to existing legal scholarship by adding an interdisciplinary perspective based on political epistemology.[26] Current legal approaches to EU agency transparency are evaluated against the background of the concept of expert accountability developed in interdisciplinary research on the role of specialized knowledge in public decision-making. According to the latter, experts working in regulation should publicly explain and justify their scientific judgements to allow public scrutiny, which in turn requires wide access to the scientific information underlying these judgements. Adding such an external perspective allows us to go beyond doctrinal critique by probing the assumptions on which EU legal rules and judicial interpretations are built against the institutional dynamics and challenges of EU risk regulation. The methodological contribution of the article, therefore, lies in the combination of doctrinal analysis and interdisciplinary insights. It

23. Korkea-aho and Leino-Sandberg, op. cit. *supra* note 15; Ní Chearnaigh, "Piecemeal transparency: An appraisal of Regulation (EU) No. 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain", 12 EJRR (2021), 699–710.

24. Korkea-aho and Leino-Sandberg, op. cit. *supra* note 15.

25. See also Curtin and Leino-Sandberg, op. cit. *supra* note 12.

26. This is inspired by social-legal or new legal realist approaches, according to which the meaning and normative functions of legal concepts are studied within the specific institutional contexts in which such concepts operate. See e.g. Nourse and Shaffer, "Varieties of new legal realism: Can a new world order prompt a new legal theory?", 95 *Cornell Law Review* (2009), 61–138.

deviates from top-down scholarly approaches, whereby EU rules and practices are measured against transparency as a constitutional principle laid down in the Treaty. The value of such approaches is not denied. Like most constitutional principles, however, transparency is an open-textured norm, whose meaning is shaped by legal and institutional practices which operate contextually, i.e. against the background of different public functions and procedures, as well as often conflicting interests. Therefore, transparency remains an ambiguous principle in EU law.[27] To form normative expectations towards what transparency should accomplish in EU law and governance, it is crucial to study its meaning and function in concrete institutional contexts.

The article begins by analysing the traditional "passive" approach to transparency. Section 2 outlines the basic principles of the Access Regulation before analysing recent case law of the EU courts on general presumptions in the field of EU risk regulation. Section 3 discusses the role of the Aarhus Regulation in providing access to environmental information held by EU agencies. Section 4 delves into sectoral legislation, which governs the transparency of information held by the three most important risk regulation agencies, the European Medicines Agency, the European Food Safety Authority, and the European Chemicals Agency. It offers a comparative analysis of the transparency regimes of these agencies, including their inconsistencies, as well as the recent emergence of "proactive transparency" in both sectoral legislation and agency practice. Section 5 juxtaposes our findings with interdisciplinary insights, which show the importance of "proactive transparency" for holding EU experts to account. Finally, the conclusion summarizes the main findings.

2. Agency science and the EU Access Regulation: The privileging of administrative secrecy

In the EU legal order, transparency has gained constitutional status as an essential prerequisite of citizen participation in EU decision-making, and thus of the effective application of the principle of democracy.[28] Transparency is part and parcel of the EU's normative commitments to democratic principles of representative and participatory democracy,[29] which in turn entail the right of "every citizen" "to participate in the democratic life of the Union", as well as that decisions are "taken as openly and as closely as possible to the

27. Mendes, op. cit. *supra* note 6.

28. Lenaerts, "The principle of democracy in the case law of the European Court of Justice", 62 ICLQ (2013), 271–315, 277; Prechal and De Leeuw, op. cit. *supra* note 12.

29. Title II TEU, in particular Art. 10.

citizen".[30] These constitutional commitments have been given effect, among other means, through the codification of the fundamental right of access to documents[31] in the Access Regulation as well as through a longstanding line of case law from the EU courts.[32]

In this section, we discuss the "traditional" EU approach to transparency represented by the Access Regulation and its application to agency science. As usual, the ECJ's interpretation of the Regulation has significantly shaped this approach. One of the most criticized aspects of the case law on access to documents has been the creation by the ECJ of so-called general presumptions of confidentiality for certain types of documents. This line of case law, although not yet fully settled, shows a marked preference for protecting confidentiality where the latter benefits the EU administrative process, in strong contrast to its democracy-enhancing approach to the transparency of the EU legislative process. In the field of risk regulation, where administrative rule-making is both dominant and of high public interest in terms of health and environmental protection, this represents a missed opportunity for strengthening the transparency of EU regulatory science.

The Access Regulation codifies, in Article 2, the right of any Union citizen to obtain access to all documents held by any EU institution that are "drawn up or received by it and in its possession, in all areas of activity of the European Union". Because EU agencies are bodies rather than institutions, the Regulation does not apply to them directly. Instead, access to documents held by EU agencies, including scientific information, which they have gathered or received from third parties in the process of administrative procedures, is governed by several sectoral regulations. The latter generally incorporate the provisions and principles of the Access Regulation, albeit sometimes with significant variation. There is thus no single EU legal framework governing access to documents held by EU agencies. Rather, the scope and nature of access rights in this area are determined by an interplay between the Access Regulation and sectoral provisions. Therefore, the actual meaning of transparency in this field differs depending on the agency and the procedure concerned.

The general legal framework of the Access Regulation aims to ensure the "widest possible access to documents"[33] while also protecting several public and private interests, thereby achieving a balance between disclosure and

30. Art. 10(3) TEU. On transparency as an element of the principle of openness, Alemanno, op. cit. *supra* note 12.

31. Art. 42 CFR; see also Art. 15(3) TFEU.

32. See Joined Cases C-39 & 52/05 P, *Sweden and Turco* v. *Council*, EU:C:2008:374; Case C-280/11 P, *Council* v. *Access Info Europe*, EU:C:2013:671; Case T-540/15, *Emilio de Capitani* v. *European Parliament*, EU:T:2018:167; see also Lenaerts, op. cit. *supra* note 28.

33. Art. 1(a) Access Regulation.

confidentiality. Therefore, the principle of widest possible access may be departed from where an exception under Article 4 applies. Two exceptions are particularly relevant for access to agency science, namely the "commercial interests" exception under Article 4(2) (first indent) and the "space to think" exception under Article 4(3).[34] The "commercial interests" exception allows institutions to refuse access where disclosure would undermine a natural or legal person's commercial interests. In EU authorization procedures, third parties are mostly companies that have submitted scientific data and other information as part of their marketing application. Before granting access to such information and in order to determine whether the exception applies, the company must be consulted[35] and in that process will often invoke the protection of a commercial interest or intellectual property rights.

The "space to think" exception applies where the documents to be disclosed are part of an ongoing decision-making procedure, in which the final decision has not yet been taken and where disclosure would seriously undermine the decision-making process. That also typically applies in authorization procedures, given that the agency advice is only an intermediate procedural step towards the final decision taken by other EU institutions, most notably the European Commission.

Restrictions to the right of access based on these exceptions may be overcome where the person seeking access is able to prove an overriding public interest in disclosure. According to established case law,[36] such exceptions must be interpreted and applied narrowly.[37] However, the ECJ has seriously tampered with this principle through the creation of general presumptions of confidentiality. Ordinarily, when deciding whether a document is covered by an exception to access, institutions are obliged to examine specifically and individually whether that document falls within an exception. However, beginning with its *obiter* statement in the 2008 case *Sweden and Turco,* and then confirmed two years later in *TGI*, the ECJ has developed a concept of general presumptions of confidentiality.[38]

34. Other mandatory exceptions include the public interest in public security, defence and military matter, international relations and the financial, monetary or economic policy of the Union or a Member State as well as the privacy and integrity of the individual (Art. 4(1) Access Regulation).

35. Art. 4(4) Access Regulation.

36. Case C-280/11 P, *Council* v. *Access Info Europe*, EU:C:2013:671, para 30.

37. See *infra* section 4.

38. Joined Cases C-39 & 52/05 P, *Sweden and Turco*, para 50; Case C-139/07 P, *TGI*, EU:C:2010:376. See Rossi and Vinagre e Silva, *Public Access to Documents in the EU* (Hart, 2017), pp. 152 et seq.; and Adamski, "Approximating a workable compromise on access to official documents: The 2011 developments in the European Courts", 49 CML Rev. (2012), 521–558.

General presumptions entitle institutions in certain cases to presume that an exception to access applies, without being obliged to examine specifically and individually whether each of the documents requested falls under that exception. Documents must belong to certain judicially recognized categories, the ECJ reasoning that similar considerations of confidentiality are likely to apply to documents of the same nature.[39] The ECJ has recognized general presumptions in an array of administrative proceedings, namely State aid,[40] merger control,[41] cartels,[42] infringement proceedings,[43] and EU pilot proceedings.[44] General presumptions may appear attractive from the point of view of administrative efficiency and resourcing, allowing institutions to filter requests. The ECJ tends to justify general presumptions with the need to protect certain types of administrative procedures, considering their special nature. For example, in State aid cases, sectoral rules adopted by legislation governing access to an administrative file are designed to protect the legitimacy and effectiveness of the State aid procedure. Such carefully designed procedures might be jeopardized by excessive encroachment of access to documents rights under the Access Regulation. Early cases recognizing general presumptions related to procedures with specific rules governing access to a file set out in legislation.[45] However, more recently the ECJ has expanded such presumptions also to proceedings without sectoral rules governing access to the file (namely infringement and pilot proceedings).[46] The application of general presumptions where no such sectoral rules exist seems less justifiable, as it leaves general presumptions in the sole hands of the relevant institution or agency, and has no basis in legislation.[47]

While we recognize the need to balance concerns of functionality with the public interest of access to document, the burden of general presumptions on those seeking access should be acknowledged. They must prove an overriding public interest in disclosure of documents they have not had sight of. General presumptions have no basis in the Access Regulation or the Treaties and have

39. Case C-139/07 P, *TGI*, para 54.
40. Ibid.
41. Case C-404/10 P, *Éditions Odile Jacob,* EU:C:2012:393.
42. Case C-365/12 P, *EnBW Energie Baden-Württemberg AG*, EU:C:2014:112.
43. Case C-605/11 P, *LPN and Finland* v. *Commission*, EU:C:2013:738.
44. Case C-562/14 P, *Sweden* v. *Commission*, EU:C:2017:356.
45. See e.g. Case C-139/07 P, *TGI*; Case C-404/10 P, *Éditions Odile Jacob*; Case C-365/12 P, *EnBW Energie AG*.
46. See Case C-605/11 P, *LPN*; and Case C-562/14 P, *Sweden* v. *Commission*.
47. On this point, see Mendes, op. cit. *supra* note 6, at 19.

been repeatedly criticized for overly curtailing the right of access.[48] Against this background, the ECJ's expansion of general presumptions to a wider array of procedures should be watched critically. In fact, in the absence of specific rules governing access to the file, it is more difficult to reconcile concerns around the functioning of administrative procedures with the democratic underpinnings of the right of access.[49] In some cases, such as risk regulation, as we discuss below, general presumptions might be altogether counterproductive to the proper functioning of administrative procedures, because of the negative effects of administrative secrecy on the epistemic quality of EU administrative decisions as well as on public trust.

In contrast, by reference to democratic principles, the ECJ has so far rejected attempts to assert general presumptions of confidentiality over documents in legislative proceedings. In *TGI*, the ECJ held that "where the Community institutions act in the capacity of a legislature . . . wider access to documents should be authorized ….".[50] Such wider access also applies to documents that, while not part of the legislative process per se, are closely linked to it. In *ClientEarth* v. *Commission*,[51] the ECJ refused to recognize a general presumption over impact assessments and related documents (some of them draft) intended to assist the Commission in drawing up legislative proposals.[52] It held that such documents form "part of the basis for the legislative action of the European Union"[53] and emphasized democratic principles, stating that disclosure of the documents would increase transparency and openness of the legislative process, allowing citizens to scrutinize the information and attempt to influence the process.[54] In contrast to documents in administrative procedures, democratic principles in the legislative process outweigh, in the ECJ's reasoning, any functional necessities or even the need to protect the effectiveness of the EU legislative process. This reasoning is open to challenge. On the one hand, given its institutional complexity, it is not obvious that functional arguments should

48. Adamski, op. cit. *supra* note 38, 526; Curtin and Leino-Sandberg, op. cit. *supra* note 12; Craig, *EU Administrative Law*, 2nd ed. (OUP, 2012), p. 363; and Mendes, op. cit. *supra* note 6, at 13–14 and 16–17.

49. Similarly Mendes, op. cit. *supra* note 6.

50. Case C-139/07 P, *TGI*, para 60. See generally Adamski, op. cit. *supra* note 38.

51. Case C-57/16 P, *ClientEarth* v. *Commission*, EU:C:2018:660.

52. Ibid., paras. 109, 112. The ECJ first held that although the Commission must be able to enjoy space for deliberation, it was not entitled to apply a general presumption of confidentiality. The ECJ held that the fact that the documents in question were merely provisional also did not create a general presumption (para 111), and the fact that the process was at an early stage did not demonstrate a reasonably foreseeable risk that access would undermine the process (para 112).

53. Ibid., para 91.

54. Ibid., paras. 92, 108.

never apply to the EU legislative process outweighing the interest in disclosure. On the other hand, given their opaque nature and their distance from democratic processes, one could argue that transparency is even more important in administrative procedures, as opposed to the legislative process, since the latter is carried out by directly elected representatives and is typically accompanied by a higher level of public attention. In fact, at national level, transparency rules are designed to improve the transparency of public administration rather than that of the legislature, the former being considered more removed from the public eye.[55]

2.1. *General presumptions to protect the administrative space to think*

In the domain of risk regulation, the ECJ has not yet definitively considered whether the EFSA, EMA or ECHA may apply general presumptions to protect their space to think in authorization procedures. Some initial case law suggested that they do not have this option. In *Borax*, the General Court (GC) held that scientific opinions given in the context of a comitology procedure to classify certain substances as dangerous were not subject to the space to think exception.[56] However, at this point, general presumptions were still in their infancy – the judgment in *Sweden and Turco* was delivered less than a year previously and the many subsequent judgments which fully fleshed out the concept of general presumptions had not yet been given.

More recently, the GC has signalled willingness to allowing risk regulation agencies to invoke general presumptions to protect their space to think. In *MSD*, the GC left open the possibility that a general presumption of non-disclosure could apply in authorization procedures as long as a decision-making process was ongoing, so as to protect the agency's space to think.[57] The GC acknowledged that "the application of general presumptions may be dictated by the overriding need to ensure that the procedures at issue operate correctly and to guarantee that their objectives are not jeopardized".[58] This includes where intervention of third parties risks undermining the

55. See Dragos et al., "A brief comparative outlook on the regulation of parties, procedure and exceptions in different FOIAs" in Dragos et al. (Eds.), *The Laws of Transparency in Action: A European Perspective* (Palgrave, 2019), pp. 599–638; Curtin, "Judging EU secrecy", 2 CDE (2012), 459–490 at 481.

56. Case T-121/05, *Borax Europe*, EU:T:2009:64, paras. 67–71. The GC rejected the Commission's arguments that disclosure presented a risk to the process as being general and abstract and held that the Commission was obliged to specify how disclosure would concretely and effectively undermine the process.

57. Case T-729/15, *MSD*, EU:T:2018:67, paras. 26, 27 and 32.

58. Ibid., para 26.

procedure.[59] However, those statements were *obiter,* as the procedure in *MSD* had concluded and on appeal the ECJ did not deal with this point.[60]

At the same time, and in a somewhat contrasting fashion, both the GC and Court of Justice have also recently begun to recognize the importance of openness and democracy in agency scientific decision-making. In *Tweedale*, *Hautala*, *PTC* and *MSD* – all cases concerning access to documents in administrative proceedings – both courts gave cursory acknowledgment of the role of openness which "enables the EU institutions to have greater legitimacy and to be more effective and more accountable to EU citizens in a democratic system …".[61] However, whether these statements will have any real consequences for access to documents in risk regulation remains open. Currently, concerns for democracy and openness remain far more pervasive in cases pertaining to legislative documents than in any of these cases.[62] Moreover, although disclosure was made in *Tweedale* and *Hautala*, these cases concerned access to environmental information under the Aarhus Regulation (see section 3 below) to which special provisions apply. Likewise, *MSD* and *PTC* concerned commercial interests rather than space to think (although the litigant companies erroneously sought to invoke the latter exception).

General presumptions already apply to protect administrative space to think in a host of areas. Considering the GC's comments in *MSD,* if agencies can convince the ECJ of an overriding need to ensure that procedures operate correctly by limiting third-party intervention, it may be possible that they will be able to establish a general presumption that disclosure of certain information will undermine ongoing authorization proceedings.

When compared to the ECJ's preference for legislative openness, such privileging of administrative secrecy would be problematic in risk regulation. While authorization proceedings are administrative in nature, they mostly involve general rule-making and standard setting which affects people and the environment at large. Moreover, for reasons discussed below (section 5), transparency is central to holding EU regulatory science to account. Though

59. Ibid.

60. Case C-178/18 P, *MSD*, EU:C:2020:24. See also Hickey, "We can only presume: Relationship between protection of commercial interests and general presumptions of confidentiality shrouded in mist as Court of Justice upholds EMA disclosure of clinical study reports", 12 EJRR (2021), 871–878.

61. Case T-716/14, *Tweedale*, EU:T:2019:141, para 54; Case T-329/17, *Hautala*, EU:T:2019:142, para 60; Case C-175/18 P, *PTC Therapeutics International* v. *EMA*, EU:C:2019:709, para 53; Case C-178/18 P, *MSD*, para 50. See Morvillo, "The General Court orders disclosure of glyphosate-related scientific studies: *Tweedale*, *Hautala*, and the concept of environmental information in the context of plant protection products", 10 EJRR (2019), 419–427.

62. See e.g. Joined Cases C-39 & 52/05 P, *Sweden and Turco*, paras. 34, 45–46, 59, 65–67.

administrative in nature, a grant of authorization can have far-reaching consequences for the general population in sensitive domains like public health and the environment. In terms of their effects, therefore, marketing authorization decisions are unlike many other kinds of administrative decisions. While citizens and civil society organizations can examine documents over which Article 4(3) of the Access Regulation was asserted once the authorization procedure is concluded, at this stage the proverbial horse may have bolted, and potentially harmful substances may already have been approved.

The functionalist concerns of protecting the effectiveness of EU law and integration which general presumptions ordinarily serve[63] could actually be undermined if agency opaqueness contributes to citizens no longer trusting agency decisions, as the glyphosate controversy demonstrates. This risk is widely recognized in current EU policy debates. Accordingly, there is a strong case for extending the ECJ's high standards of legislative transparency to the field of risk regulation. At a minimum, the ECJ should refuse to allow agencies to invoke a general presumption that disclosure of documents before the end of the authorization process would undermine administrative space to think under Article 4(3) of the Access Regulation. Such an approach would moreover be in line with the recent trend towards proactive transparency and full dissemination of scientific information at the moment of the filing of an authorization application as adopted under the new General Food Law, as we discuss further below.

2.2. *General presumptions to protect commercial interests*

The ECJ's privileging of administrative secrecy is also visible when we compare its treatment of administrative interests with its treatment of commercial interests. While the ECJ has held that a general presumption can protect the EU executive's space to think in a wide range of circumstances, for the moment it appears that agencies cannot invoke general presumptions to protect authorization holders' commercial interests, although the point is, as we discuss below,[64] somewhat uncertain. Commercial interests are particularly salient in risk regulation. As part of the authorization process, industry applicants submit dossiers of data which are assessed by the agency; much of this data is commercially sensitive. Agencies frequently receive access requests for this data from competitor companies, who hope to gain a commercial advantage. For example, in 2019 and 2020 around 40 percent of

63. See Mendes, op. cit. *supra* note 6.
64. See *infra* section 4.

all access requests received by the EFSA came from industry.[65] This presents a potential threat to applicants' commercial interests, who fear that commercially sensitive information will be disclosed.

The ECJ has repeatedly stated that in all cases where it has found a general presumption, "the refusal of access in question related to a set of documents which were clearly defined by the fact that they all belonged to a file relating to ongoing administrative or judicial proceedings".[66] This is clearly a reference to space to think and appears to exclude the possibility that general presumptions could protect categories of document on the basis of their perceived commercially sensitivity.

However, whether documents must relate to ongoing administrative or judicial proceedings for a general presumption to apply was recently contested by Advocate General Hogan in the appeal cases *PTC* and in *MSD*. Advocate General Hogan instead proposed a broad and versatile test that would have permitted a general presumption wherever it was "reasonably foreseeable that disclosure of the type of document falling within [a particular] category would be liable actually to undermine the interest protected by the exception in question".[67] According to Advocate General Hogan, general presumptions should apply to avoid undermining *any* protected interest, including commercial interests. Although the ECJ in *PTC* and *MSD* sidestepped the question of whether general presumptions can protect commercial interests, the fact remains that all proceedings in which general presumptions have been recognized by the ECJ were administrative or judicial in nature.

If the "ongoing administrative or judicial proceedings" wording is not a criterion for applying a general presumption, it is difficult to understand why the ECJ keeps restating it. It is also worth noting that the ECJ judgment from which Advocate General Hogan purported to draw a broader test, *Client Earth,* also reiterated the "ongoing administrative or judicial proceedings" wording – something the Advocate General did not mention.[68] Moreover, *ClientEarth* concerned an ongoing procedure and did not concern protection

65. ECHA, "Access to documents at ECHA – 2019 key figures", available at <echa.europa.eu/documents/10162/13604/atd_2019-key-figures_en.pdf/195abe9f-b4aa-d729-a2a3-d05191edd144>; and ECHA, "Access to documents at ECHA – 2020 key figures", available at <poisoncentres.echa.europa.eu/documents/10162/13604/atd_2020-key-figures_en.pdf/28f961d7-1a20-1448-9539-33dac30b83d0>. See also Mendes, op. cit. *supra* note 6, at 11–13. For a comparison with the use of lobby registers, see Crepaz, "To inform, to strategise, collaborate, or compete: What use do lobbyists make of lobby registers?", 12 *European Political Science Review* (2020), 347–369.

66. See e.g. Case C-57/16 P, *ClientEarth*, para 81; Case C-562/14 P, *Sweden* v. *Commission*, para 44.

67. Opinions of A.G. Hogan in Case C-175/18 P, *PTC*, EU:C:2019:709, para 70, and in Case C-178/18 P, *MSD*, EU:C:2019:710, para 50.

68. Case C-57/16 P, *ClientEarth*, para 62.

of commercial interests. In any case, even if the test proposed by Advocate General Hogan is the correct one,[69] the ECJ has yet to recognize a general presumption in favour of parties' commercial interests but has recognized general presumptions to protect administrative interests in a host of areas.

If the ECJ were to recognize general presumptions as covering commercial interests, this would be problematic in risk regulation. There are concerns about the reliability of scientific information submitted by applicant companies and a broader policy debate about the appropriate role of economic actors as information providers in EU risk regulation.[70] General presumptions in favour of companies' commercial interests would undermine public scrutiny of information submitted as part of the application process, because in many ways the commercial interests exception is stronger than the exception for a space to think. For instance, space to think is inherently limited in time, as it ceases to apply once a final decision has been taken. By contrast, a commercial interest can in principle continue indefinitely and its existence will depend heavily on an authorization holder's individual commercial circumstances. Further, the threshold under Article 4(3) for the space to think exception to apply is higher than the threshold for the commercial interests exception under Article 4(2). The former requires a risk that the agency's space to think be "seriously undermined" whereas the latter requires only that the applicant's commercial interests are "undermined".[71] Allowing agencies to invoke general presumptions to protect applicants' commercial interests would accordingly have a far more invasive impact on public scrutiny and accountability of regulatory science. Even though many of the access to document requests come from competitors, a significant number also come from citizens, civil society organizations, and academia.

Finally, it is worth noting that from the point of view of administrative efficiency and resourcing, the application of the commercial interests exception is less onerous for agencies. This is because authorization holders (typically well-resourced corporations) whose information may be disclosed, are asked to identify commercially sensitive portions of a requested document. The agency then has the (usually) more straightforward task of determining whether the authorization holder's proposed redactions are in fact commercially sensitive.[72] By contrast, in applying space to think, an

69. See also Hickey, op. cit. *supra* note 60.

70. See Robinson et al., "Achieving a high level of protection from pesticides in Europe: Problems with the current risk assessment procedure and solutions", 11 EJRR (2020), 450–480; Morvillo and Weimer, "The CJEU and epistemic power of economic actors in EU risk regulation", draft paper on file with the authors.

71. This was confirmed on appeal in Case C-175/18 P, *PTC,* para 90.

72. This assumes, however, that the company's proposed redactions are reasonable and relatively narrow, reducing the number of proposed redactions for the agency to review. This

agency would in principle be obliged to examine an entire document to determine which portions might jeopardize its ongoing decision-making processes. This might explain the ECJ's hesitance to allow general presumptions in the former case but not the latter.

3. Agency science and the Aarhus Regulation: The privileging of environmental information

Regulation 1367/2006/EC (the Aarhus Regulation) introduces a further degree of differentiation into the access to documents legal landscape by strengthening access rights regarding environmental information. On the one hand, the Regulation shows the importance of transparency in the environmental domain as well as the close link between environmental protection, public participation, and trust. On the other hand, it further demonstrates the privilege accorded to administrative secrecy, mainly because it mandates absolute standards of openness where commercial confidentiality is asserted over certain environmental information, but not where "space to think" exceptions are asserted.

The Aarhus Regulation was enacted to meet the Union's obligations under international law, namely the Aarhus Convention (the Convention).[73] Unlike Regulation 1049/2001, which only directly binds EU "institutions", the Aarhus Regulation applies to environmental information held by the EU's "institutions and bodies"[74] and therefore includes the agencies. The Aarhus Regulation aims to protect and improve environmental quality and human health,[75] as well as to promote public participation in environmental decision-making. The preamble to the Convention also mentions the aim of strengthening democracy. Both instruments cite accountability and strengthening public support for and trust in environmental decision-making as core aims.[76] To further these aims, the Aarhus Regulation contains

would not be the case where companies claim that either the entirety or very extensive portions of a lengthy document are commercially sensitive. For an example of this see Case C-175/18 P, *PTC*.

73. Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, done at Aarhus, Denmark on 25 June 1998; Regulation (EC) 1367/2006 of the European Parliament and of the Council of 6 Sept. 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (the Aarhus Regulation), O.J. 2006, L 264/13–19.

74. Arts. 1(a) and 3 Aarhus Regulation.

75. Recital 1, Aarhus Regulation.

76. Recital 2, Aarhus Regulation.

measures to increase transparency.[77] It is therefore closely linked to the objective of improving the public accountability of regulatory science, which, as we discuss below (section 5), is based on the assumption that science advice used in regulation should be scrutinized not only through internal scientific boards employed by public agencies, but also by independent scientists, civil society, affected citizens, and other stakeholders.

The Aarhus Regulation *inter alia* guarantees the public's right of access to environmental information received or produced by EU institutions or bodies,[78] and ensures institutions and bodies actively disseminate certain environmental information.[79] One of the key features of the Aarhus Regulation is its special provisions on information relating to "emissions into the environment". The first sentence of Article 6(1) of the Aarhus Regulation provides that "an overriding public interest in disclosure shall be deemed to exist where the information requested relates to emissions into the environment" in cases falling under the first indent (protection of commercial interests) and third indent (purpose of inspections, investigations and audits) of Article 4(2) of the Access Regulation.

The ECJ has given a generous interpretation to the meaning of "emissions into the environment". In *Greenpeace* v. *Commission (Glyphosate)*[80] the ECJ held that Article 6(1) of the Aarhus Regulation should be given the broadest possible meaning, following the principle of widest possible access to documents.[81] It then rejected the Commission's argument that "emissions into the environment" was restricted to emissions emanating from industrial installations such as factories and power stations, and held that "emissions" could include emissions of pesticides into the environment.[82] It moreover concluded that the notion of "emissions into the environment" is not limited to information relating to *actual emissions* but may also cover information relating to *foreseeable emissions*.[83] Foreseeable emissions means emissions foreseeably released under normal or realistic conditions of use of the substance in question, namely the conditions under which it received authorization and which prevail in the area of intended use.[84]

77. For an analysis of the relationship between participatory democracy, effectiveness and public acceptance of environmental decision-making in a system of multilevel governance, see Newig and Fritsch, "Environmental governance: Participatory, multi-level – and effective?", 19 *Environmental Policy and Governance* (2009), 197–214.
78. Art. 1(a) Aarhus Regulation.
79. Art. 1(b) Aarhus Regulation.
80. Case C-673/13, *Greenpeace*, EU:C:2016:889.
81. Ibid., paras. 50–55.
82. Ibid., para 62.
83. Ibid., paras. 71–76.
84. Ibid., para 75.

In *Bayer CropScience*,[85] which it delivered on the same day, the ECJ held that "emissions into the environment" further includes "data concerning the medium to long-term consequence of those emissions on the environment, in particular information relating to residues in the environment …, and studies on the substance's drift during that application".[86] It later reaffirmed this in *Blaise,* holding that the Aarhus Regulation was "applicable . . . to a great extent, to the studies designed to assess the harm that may be caused by the use of a [pesticide] or the presence in the environment of residues after the application of that [pesticide]".[87]

This finding was affirmed and bolstered by the GC in *Hautala*[88] and *Tweedale.*[89] There, the applicants sought access to studies used by the EFSA to assess the carcinogenicity of glyphosate in the Commission's controversial decision to reapprove the substance. In both cases, the EFSA granted access to the studies' raw data, but refused to disclose information relating to experimental conditions, methods, and discussion of the studies, on the basis that it was commercially sensitive. The EFSA considered that there was no overriding public interest because the information already disclosed met any such interest, and the information did not constitute emissions into the environment.[90]

The GC reiterated that emissions into the environment also include information relating to those emissions' effects.[91] It emphasized that the public must have a reasonable opportunity to understand how the environment could be affected, meaning access to studies, not just their raw data.[92] It accordingly found an overriding public interest in disclosure.[93] The GC rejected as irrelevant the argument that the raw data was sufficient to allow the public to verify results.[94] It confirmed that protection of commercial interests could not prevent disclosure of information relating to emissions into the environment under Aarhus.[95]

The net effect of Article 6(1) and its interpretation by the EU Courts is that citizens have a powerful tool to access a wide range of environmental information, including entire reports submitted as part of agency assessments. Where an agency or an applicant asserts the commercial interests exception,

85. Case C-442/14, *Bayer CropScience*, EU:C:2016:890.
86. Ibid., para 96.
87. Case C-616/17, *Blaise*, EU:C:2019:800, para 108.
88. Case T-329/17, *Hautala*.
89. Case T-716/14, *Tweedale*.
90. Case T-329/17, *Hautala*, paras. 23–24.
91. Ibid., paras. 99, 106.
92. Ibid., paras. 121, 97.
93. Ibid., paras. 122, 123.
94. Case T-716/14, *Tweedale,* para 121.
95. Ibid., paras. 126–128.

Article 6(1) always deems an overriding public interest to apply,[96] essentially creating an irrefutable right of access.

Yet, Article 6(1) is less helpful to applicants where an agency asserts that disclosure would jeopardize its space to think, even where information relates to emissions. Unlike with commercial interests, an overriding public interest is not automatically deemed to exist in such circumstances, because the second sentence of Article 6(1) merely provides that all other exceptions under Article 4 of the Access Regulation "shall be interpreted in a restrictive way, taking into account the public interests served by disclosure and whether the information requested relates to emissions into the environment". Accordingly, in such circumstances the existence of an overriding public interest will be determined case-by-case and is never automatic.[97]

In *ClientEarth* v. *Commission*, albeit in a legislative context, the ECJ overturned the GC's finding that an environmental impact assessment was entitled to a general presumption that disclosure would seriously undermine the Commission's ongoing decision-making process. The ECJ invoked the second sentence of Article 6(1) to conclude that exceptions must be interpreted strictly where the request concerns environmental information.[98]

Would similar reasoning apply to documents in administrative procedures? There is no basis in the Aarhus Regulation to treat administrative documents differently from legislative ones.[99] The requirement under Article 6(1) to interpret exceptions restrictively, combined with the ECJ's recent recognition of openness and participatory democracy in agency proceedings,[100] might protect the right of access to environmental information held by agencies from general presumptions of confidentiality. Yet, we should not forget that the general requirement to interpret exceptions restrictively has not stopped the ECJ from recognizing general presumptions in other areas. Indeed, there is similarly no basis in the Access Regulation for treating legislative documents differently from administrative ones, but the ECJ nonetheless does so. Accordingly, it is still unclear whether the standard of openness applied to environmental information in *ClientEarth* v. *Commission* will be transposed to agencies when dealing with emissions into the environment where space to think is asserted.

96. See Rossi and Vinagre e Silva, op. cit. *supra* note 38, at p. 171.

97. Ibid.

98. Case C-57/16 P, *ClientEarth*, para 100.

99. However, in Case C-57/16 P, *ClientEarth,* in addition to Art. 6 Aarhus Regulation, the ECJ also relied heavily on the increased importance of access to documents in the legislative process. See paras. 85–95, 105.

100. Case T-716/14, *Tweedale*, para 54; Case T-329/17, *Hautala*, para 60; Case C-178/18 P, *MSD*, para 50; Case C-175/18 P, *PTC*, para 53. See Morvillo, op. cit. *supra* note 61.

In sum, the Aarhus Regulation can be a significant tool in the arsenal of any applicant seeking access to environmental information. In the domain of risk regulation, *Greenpeace* v. *Commission (Glyphosate)*, *Bayer CropScience*, *Hautala* and *Tweedale* show that Article 6(1) has already been of great assistance to those seeking access to documents held by agencies in the face of commercial objections. Yet, it has limits. It is far less helpful where other exceptions are invoked (such as space to think) and can be of no assistance when it comes to health-related information. The definition of "emissions into the environment" and "environmental information"[101] can only stretch so far, despite the ECJ's generous interpretation of the former term. For example, information concerning medicines is unlikely to be considered "environmental information" or "emissions into the environment". Even certain information concerning substances such as ingredients in household cleaning products might struggle to fall within either definition. Yet, the authorization of such substances can have similarly far-reaching consequences for public health and safety, for example where such substances are carcinogenic or otherwise pose a threat to human health and safety. It is therefore difficult to see how there is any less public interest in disclosure of information in those circumstances than there is where information relates to emissions into the environment. This is not to criticize the strengthening of access rights under the Aarhus Regulation. Rather we point out the anomaly of information remaining confidential in fields like public health in which there is an analogous public interest in disclosure. The difficulties of proving an overriding public interest in disclosure together with the ECJ's already-signalled openness to recognizing general presumptions in authorization proceedings increase the difficulty of obtaining such information.

4. Sectoral fragmentation and the emergence of "proactive transparency" – ECHA, EMA, EFSA

Access to information and the transparency of EU agencies are also strongly shaped by sectoral legislation, to which we turn now. In this section, we analyse and compare the patchwork of provisions governing access to documents held by the EU's three most important risk regulation agencies: the European Chemicals Agency (ECHA), European Medicines Agency (EMA) and European Food Safety Agency (ESFA). Each of these agencies provides scientific opinions as part of authorization procedures for certain products and substances under their respective sectoral laws (which deal with chemical

101. See definition under Art. 2(1)(d) Aarhus Regulation.

products, medicinal products, and food and feed products, respectively). The scientific advice provided by these agencies is often decisive for the authorization of risk-entailing products and substances on the EU internal market. Therefore, questions of independence, epistemic quality, and transparency,[102] of the underlying scientific information are often at the forefront of debates and controversies surrounding the work of these agencies.[103]

Looking at the sectoral regulations that govern access to scientific information held by the three agencies, we see that the scope of access rights can vary depending on which agency an applicant is seeking information from. Examined against the yardstick of the Access Regulation, in some cases the sectoral regulations further limit rights of access while in other cases they set higher standards of openness than the Access Regulation. These differences create a fragmented framework of transparency provisions governing agency science, and such fragmentation is further exacerbated by variations in the actual practice between the three agencies.

To begin with, some sectoral regulations seek to create quasi-general presumptions of confidentiality[104] not foreseen in the Access Regulation by defining certain types of information as being *deemed* to be commercially confidential, and therefore justifying the denial of access. In the case of the ECHA, both the Biocides Regulation and the REACH Regulation provide such modified exceptions for the protection of commercial interests.[105] On the one hand, in *ClientEarth and ICS,* the GC accepted that Article 118 REACH created a general presumption that disclosure of precise tonnage would undermine the authorization holders' commercial interests.[106] Yet, on the other hand, it later took the opposite position in *Deza*.[107] Accordingly, in *Deza* the GC held that the ECHA was obliged to specifically and individually examine each document to consider whether it was covered by the

102. The scientific risk assessment carried out by EU agencies must therefore be excellent, independent and transparent; see Case T-13/99, *Pfizer Animal Health*.

103. E.g. in May 2012, the EP delayed approving the EFSA budget because of allegations of conflicts of interest, see "Euro MPs criticise managers of EU agencies", *BBC News*, 10 May 2012, available at <www.bbc.com/news/world-europe-18007004>; see also Robinson et al., op. cit. *supra* note 70.

104. On general presumptions see *supra* section 2.

105. Art. 66(2) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, O.J. 2012, L 167 (Biocides Regulation) and Art. 118(2) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, O.J. 2006, L 396 (REACH Regulation).

106. Case C-57/16 P, *ClientEarth*, paras. 173–175.

107. Case T-189/14, *Deza* v. *ECHA*, EU:T:2017:4, paras. 38–40.

exception.[108] Thus, whether *Deza* can be considered as overruling *ClientEarth and ICS* remains unclear, not least because the GC in *Deza* did not refer to *ClientEarth and ICS*.[109] As already discussed above,[110] general presumptions of confidentiality in risk regulation remain a distinct possibility pending further clarification by the ECJ.

Another example of a sector-specific limitation of the right to access is the fact that the REACH Regulation makes no mention of "overriding public interest". Instead, it only provides that "[w]here urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Agency may disclose the information referred to in this paragraph".[111] The ECHA's internal policy on access to documents similarly makes no mention of overriding public interests.[112] This falls far short of the requirement under the Access Regulation that exceptions to access can be overcome by proving an overriding public interest in disclosure. The REACH provision is problematic, first, because overriding public interests include circumstances which are much broader than only those requiring urgent action.[113] Second, the words "may disclose" in REACH indicate that disclosure in urgent situations is entirely discretionary on the part of the ECHA, whereas disclosure is mandatory in the case of an overriding public interest under the Access Regulation.

It is difficult to see why the EU legislature chose to enshrine lesser rights of access in these cases. While it is possible that it decided in each case for functional reasons that different standards of openness should apply, this is not fully convincing given the similarities between the three agencies in terms of their role in the risk regulatory process and the similar expectations they have towards the role of transparency in increasing trust and the legitimacy of their operation. This is even more pertinent when we consider that the same substance can be assessed by two different agencies (such as glyphosate, which was assessed by both the EFSA and ECHA). It is difficult to imagine what different commercial considerations could apply between otherwise substantially similar products. It can be speculated that these regulatory divergences are due to the ad hoc nature of how EU agencies including their founding regulations are created, which gives each industry group a separate

108. Ibid., paras. 41–42.

109. See Korkea-aho and Leino-Sandberg, op. cit. *supra* note 15, 1079.

110. *Supra* section 2.

111. Art. 118(2) REACH, final para.

112. ECHA, "Decision on the implementation of Regulation 1049/2001", MB/12/2008 adopted 25 March 2009, available at <echa.europa.eu/documents/10162/13604/mb_12_2008_final_implementing_rules_access_to_documents_en.pdf/8b081a88-4e70-447c-a069-13d953f47948>.

113. See Korkea-aho and Leino-Sandberg, op. cit. *supra* note 15, 1070.

"throw of the dice" to lobby the EU legislature to roll back transparency requirements.[114] Where certain industries are more effective at lobbying than others this may create divergent rights of access.[115]

Of the three agencies, the EMA has long sat at the more access-friendly end of the spectrum, with the EMA Regulation cleanly taking over all the principles of the Access Regulation. It provides without qualification that the Access Regulation applies to documents held by the agency and requires the Management Board to adopt measures implementing the Access Regulation.[116] Following a recommendation of the European Ombudsman,[117] the EMA has also adopted a very robust policy of proactive publication and dissemination of clinical data.[118] This is an especially far-reaching policy, which includes the proactive publication of *both* clinical study reports submitted to the Agency *and* individual patient data recorded for the purposes of a clinical study.[119]

Recent reforms mean that, at least from a legislative standpoint, the EFSA has now joined the EMA in this more proactive approach. Previously, the EFSA had represented the most striking example of legal fragmentation regarding agency science. The General Food Law (GFL) before 2021 stipulated a vague requirement that the EFSA was to ensure "wide" access to documents and mandated its Board to adopt provisions to that effect, which

114. E.g. in its first reading of Regulation 1107/2009 of the European Parliament and of the Council of 21 Oct. 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (Pesticides Regulation), O.J. 2009, L 309/1, the Parliament proposed a right of public access for interested parties through reading rooms. See EP, A6-0358/2007 "Report on the proposal for a regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market", 5 Oct. 2007, amendments 44, 100 and 211. Proposing this very limited right of access (which still fell far below the requirements of the Access Regulation), the Parliament stressed that it would strike the right balance between public access and preventing competitor misuse. This was apparently rejected by the Council in its second reading and did not make it into the final Regulation. In the debates, several MEPs rebuked industry lobbyists' role in the legislative process. See Debates of the European Parliament, 22 Oct. 2007, 23, comments of Erna Hennicot-Schoepges; and Debates of the European Parliament, 23 Oct. 2007, 43, comments of Carl Schlyter.

115. On the influence of lobbying in the EU see Eckert, *Corporate Power and Regulation* (Palgrave, 2019).

116. Regulation 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (EMA Regulation), O.J. 2004, L 136/1, Art. 73.

117. Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the EMA dated 24 Nov. 2010.

118. EMA/144064/2019, "Policy on publication of clinical data for medicinal products for human use", Policy/0070 of 21 March 2019.

119. Ibid. For a summary of the background surrounding the adoption of this policy see Way et al., op. cit. *supra* note 4.

the Board did in its 2003 Decision on Access to Documents (the EFSA Policy).[120] The pre-amendment GFL was *lex generalis* to various rules in relation to access to documents under seven specific regulations, which would apply depending on the authorization procedure in question. Some such regulations failed to provide that they were governed by the principles of the Access Regulation.[121] Others only did so in a recital, which was therefore not legally binding.[122] Because the EFSA Policy also did not align perfectly with the Access Regulation,[123] this created the bizarre and confusing situation that these Regulations purported in their preambles to be bound by the latter, but were in fact not. Only three EFSA Regulations specifically adopted the Access Regulation and were therefore governed by it.[124]

However, in direct response to the controversy surrounding the reapproval of glyphosate,[125] the EU legislature adopted amendments to the GFL with the aim of improving the transparency of EFSA risk assessments; these applied as of 27 March 2021.[126] Replacing the scattershot and varying rights of access

120. Ex-Art. 41 GFL. The Board adopted a policy under its Decision concerning access to documents of 16 Sept. 2003, available at <www.efsa.europa.eu/sites/default/files/assets/docsaccess.pdf>, which entered into force on 1 March 2004.

121. Neither the Pesticides Regulation, nor Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 Nov. 2015 on novel foods, amending Regulation (EU) 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) 258/97 of the European Parliament and of the Council and Commission Regulation (EC) 1852/2001 (Novel Foods Regulation) made such provision, O.J. 2015, L 327/1.

122. Recital 21 Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27 Oct. 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (Food Contact Materials Regulation), O.J. 2004, L 338/4, and Recital 20 Regulation (EC) 1331/2008 of the European Parliament and of the Council of 16 Dec. 2008 establishing a common authorization procedure for food additives, food enzymes and food flavourings (Food Additives, Enzymes and Flavourings Regulation), O.J. 2008, L 354/1.

123. E.g., EFSA's policy provided a wider space to think exception: whereas under Art. 4(3) of the Access Regulation access may be refused only where disclosure would "seriously undermine" the decision-making process, under Art. 3 of EFSA's policy it needed only to "undermine" the process.

124. Art. 18(5) Regulation (EC) 1831/2003 of the European Parliament and of the Council of 22 Sept. 2003 on additives for use in animal nutrition (Animal Feed Regulation), O.J. 2003, L 268/29; Art. 14(2) Regulation (EC) 2065/2003 of the European Parliament and of the Council of 10 Nov. 2003 on smoke flavourings used or intended for use in or on foods (Smoke Flavourings Regulation), O.J. 2003, L 309/1, and Art. 18(2) Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 Sept. 2003 on genetically modified food and feed (GMO Food and Feed Regulation), O.J. 2003, L 268/1.

125. See Arcuri and Hendlin, op. cit. *supra* note 19; and Paskalev, "On giving account and taking things into account: The case of Glyphosate", (2019) *TARN Working Paper Series*, 1/2019.

126. Regulation 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain amended the GFL and applied as of 27 March 2021, O.J. 2019, L 231/1.

under the old regime, the amended Article 41 GFL now simply provides that "[the Access Regulation] shall apply to documents held by the Authority", the legislature specifically recognizing the problems for transparency of the interplay between sectoral regulations.[127] This represents a significant improvement on the previous situation. It provides a single, unified set of rights and procedures for access to documents and increases the level of access where governing regulations were previously weak. But the reform goes further still.

Article 38 of the GFL is amended to move the EFSA to a new transparency model. The EFSA must proactively make available to the public "scientific data, studies and other information supporting applications, including supplementary information supplied by applicants …".[128] This is not only the most extensive obligation of proactive disclosure in this field today, but also removes the need for citizens to request information, instead obliging the EFSA to proactively disseminate it. This obligation also applies to a host of other documents held by the EFSA, including those relating to proceedings of its Board, Advisory Forum, Scientific Committee and Scientific Panels;[129] its scientific outputs and scientific studies;[130] and a summary of advice provided to potential applicants at pre-submission phase.[131]

The GFL now provides that information must be made public "without delay".[132] For studies submitted as part of an application for authorization or renewal this means a non-confidential version of such studies should be published as soon as the application is admissible.[133] This innovation seems to recognize that simply publishing summaries of studies would be inadequate. It addresses concerns around the quality and integrity of the raw data and other scientific information submitted by the industry applicant,[134] and recognizes the role of transparency as an important mechanism to allow for a public (including external scientific) scrutiny of industry-funded science.[135] It also ensures that authorship and source of scientific assessment are clearly visible, thereby preventing situations in which the agency might copy the industry's risk assessment without clear references, as happened in the case of the glyphosate reauthorization. As we discuss in section 5, proactive publication of full studies facilitates the kind of robust public scrutiny necessary to

127. See Recital 26 of Regulation 2019/1381.
128. New Art. 38(1)(c) GFL.
129. New Art. 38(1)(a) GFL.
130. New Art. 38(b) and (d), and (f) GFL, respectively.
131. New Art. 38(i) GFL.
132. New Art. 38(1), second indent GFL.
133. New Art. 39b(1)(a) GFL
134. See generally Robinson et al., op. cit. *supra* note 70.
135. Ibid., 470.

improve epistemic quality by independent scientists (such as those affiliated with NGOs and universities), citizens and journalists, who are now able to access all the information underpinning an application (albeit with limited and proportionate redactions, as the GFL provides for). Importantly, an immediate publication at the moment of application removes the potential obstacles created by the space to think exception under the Access Regulation. Here, the GFL takes a starkly different direction from the latter.

Other provisions of the amended GFL further facilitate public scrutiny. Information should be published in "a dedicated section of [EFSA's] website" which must "be publicly available and easily accessible" and the information must be capable of being "downloaded, printed and searched through in an electronic format".[136] Moreover, Article 32c provides that the EFSA must consult stakeholders and the public in respect of applications for authorization or renewal. In the case of applications for new substances, the public is to be consulted on non-confidential data or studies forming part of the application to determine whether there are other relevant data or studies.[137] A new Article 32d also provides a mechanism where, in cases of serious controversy or conflicting results, the Commission may request EFSA to commission studies to verify evidence used in the risk assessment process, thus resolving any conflict of evidence which could arise as a result of Article 32c.[138] These new mechanisms acknowledge the role of the public as relevant information provider and scrutinizer. They also provide for the resolution of scientific conflicts, whereby the EFSA will fund its own research in cases where there is a conflicting external scientific opinion, for example on the part of another international scientific body. Lastly, Article 32c should be able to address the problem of applicants for authorization "cherry picking" favourable studies for submission to the EFSA.[139]

Article 39 still provides certain confidentiality requirements, *inter alia* that applicants may request that certain information be kept confidential including information regarding links between producer and authorization holder;[140] sourcing, market share or strategy;[141] manufacturing processes;[142] and quantitative composition of the substance.[143] However, there is an overriding public interest provision. Information in relation to the manufacturing process and quantitative substance composition cannot be kept confidential where it is

136. New Art. 38(1), third indent GFL.
137. New Art. 32C(2) GFL.
138. Ní Chearnaigh, op. cit. *supra* note 23, 707.
139. See Robinson et al., op cit *supra* note 70.
140. Art. 39(2(b) GFL.
141. Art. 39(2)(c) GFL.
142. Art. 39(2)(a) GFL.
143. Art. 39(2)(d) GFL.

relevant to assessing safety.[144] Moreover, the applicant must demonstrate that disclosure would "harm its interests to a *significant degree*"[145] – a higher threshold than under the Access Regulation. These provisions adjust the balance between the rights of applicants and those seeking access in favour of the public interest in safety, which aligns with the principle of the high level of protection of public health and the environment in the EU.[146] They are a potentially powerful tool in the hands of those seeking information around potentially dangerous substances.

Finally, before the EFSA provides scientific outputs it must now review whether information that has been previously accepted as confidential may nevertheless be made public.[147] This means the EFSA is obliged to constantly review its decisions concerning confidentiality and may, for example, mean that it must reconsider a decision to keep information confidential considering new scientific knowledge, facts or CJEU case law. To date, the EFSA has also adopted several practical policies and guidelines in relation to transparency.[148] One of the most notable innovations among these is a commitment to interpret provisions on confidentiality "strictly, so as not to defeat the application of the principle of proactive transparency".[149]

The GFL reform significantly increases the EFSA's transparency and has been rightly referred to as the "gold standard" in EU transparency rules more generally.[150] As our analysis shows, it is now the ECHA that appears to be the laggard in terms of transparency of its agency science.

5. Transparency and expert accountability: Towards a proactive approach

The findings discussed above show the rather ambiguous role EU law plays when putting transparency as a constitutional ideal into practice in the field of risk regulation. On the one hand, the normative value of transparency for the democratic legitimacy of EU institutions is today widely accepted in EU legal-constitutional debates, whereby transparency in its ideal version is seen

144. Art. 39(2)(a) and (d) GFL.
145. Art. 39(2) GFL
146. See Arts. 9, 114(3) and 168(1) TFEU and the second sentence of Art. 35 CFR.
147. Art. 39C GFL.
148. See EFSA, "Transparency Regulation: Practical Arrangements", available at <www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>.
149. Decision of the Executive Director of the EFSA laying down practical arrangements concerning confidentiality in accordance with Arts. 7(3) and 16 of Regulation (EC) 1107/2009, Art. 3(2).
150. Hofmann and Leino-Sandberg, op. cit. *supra* note 12; Ní Chearnaigh, op. cit. *supra* note 23.

as enabling citizen participation and open decision-making. This is reflected in EU Treaty provisions and ECJ case law, and has been widely discussed in the EU legal academy.[151] On the other hand, the actual meaning and effectiveness of access rights strongly depend on both EU legislative choices, agency practices and the interpretation of secondary legislation by the EU Courts in specific cases and areas.[152] This might not be surprising. Constitutional principles, such as openness and transparency, are always shaped and given meaning within particular legal and institutional practices. Such meaning must consider different public functions and procedures, as well as often conflicting interests. In the following, such a contextual appraisal of the EU legal approach to transparency is offered. The legislative and interpretative choices analysed in this article reveal several tensions, which we critique both on legal-normative grounds (section 5.1) as well as from the perspective of political epistemology, i.e. based on interdisciplinary insights on the role of experts in risk regulation (section 5.2).

5.1. *The need for a coherent approach in EU risk regulation*

Our analysis shows that a coherent legal approach to the transparency of EU agency science is currently missing. The different approaches followed in the sectoral legislations governing access to EMA, ECHA and EFSA documents respectively result in significant variation, which is difficult to justify on functional grounds[153] given the similarities between these agencies in terms of their role in the risk regulatory process, the salience of their scientific role for managing health and environmental risks, and the substantial overlap between their spheres of operation.[154] The variation is also difficult to justify on normative grounds. All sectoral frameworks analysed refer in one way or another to the principles of the Access Regulation.[155] Moreover, the wording of Article 15(3) TFEU, the primary legal basis for the right of access to documents in the EU, indicates that there is a general right of access that can be invoked against institutions, bodies, offices, and agencies alike, and which is subject to generally defined principles and limits governing its exercise.

151. See references op. cit. *supra* notes 12 and 14.

152. They also depend on the actual willingness of the EU institutions to apply these provisions to their fullest extent. See for criticism Leino-Sandberg, op. cit. *supra* note 14.

153. See *supra* section 2.

154. It often happens that several agencies give advice on different aspects of one and the same product. That was the case for glyphosate, for which both the EFSA and ECHA carried out a scientific risk assessment.

155. See Art. 41 GFL, Art. 118 REACH, Art. 66 Biocides Regulation and Art. 73 EMA Regulation.

The different legal treatment of access to environmental as opposed to health-related information adds to further fragmentation of the legal framework governing access to agency science. Overall, the strengthening of access rights in the Aarhus Regulation is to be welcomed. At the same time, and as the COVID-19 pandemic is raging worldwide, legal provisions which would also establish an equivalent presumption of public interest in the disclosure of health-related information are arguably needed. In fact, the pandemic has amplified the importance of transparent science advice concerning health risks.[156] A recent inquiry undertaken by the European Ombudsman into the performance during the first year of the pandemic of another EU risk regulatory agency, the European Centre for Disease Prevention and Control (ECDC),[157] illustrates this. As part of this inquiry, the Ombudsman investigated how the ECDC gathers scientific information, the transparency of such information, and broader communication with the public. It found several shortcomings regarding how the ECDC collected and communicated scientific evidence underpinning its advice on pandemic measures. The Ombudsman stressed the importance of ensuring the highest standards of transparency considering the public's legitimate interest in the quality, completeness, and timeliness of the underlying scientific evidence.[158] The Ombudsman has called for a more proactive approach to transparency on the part of the ECDC, while stressing its link to accountability and public trust:

> "Transparency and accountability should be the bedrock of an institution that has a role in protecting public health. Much more should have been done to communicate with the general public to explain how and on what scientific evidence the ECDC made its assessments. Crises not only require extraordinary responses from public administrations but also extraordinary efforts to maintain public trust."[159]

156. Institute for Government, "Communications and transparency", available at <www.instituteforgovernment.org.uk/publication/whitehall-monitor-2021/transparency>.

157. The ECDC is an EU agency aimed at strengthening the Union's defences against infectious diseases. Its functions include surveillance, epidemic intelligence, response, scientific advice, microbiology, preparedness, public health training, international relations, and health communication.

158. European Ombudsman, Decision of 4 Feb. 2021 in strategic inquiry OI/3/2020/TE on how the ECDC gathered and communicated information during the COVID-19 crisis, available at <www.ombudsman.europa.eu/en/decision/en/137815>, suggestion 2.

159. European Ombudsman, Press Release No. 1/2021 published 8 Feb. 2021, "Ombudsman calls on ECDC to be more open about its work as vaccine rollout begins", available at <www.ombudsman.europa.eu/en/press-release/en/137880>.

Our analysis suggests that such a new proactive approach to transparency of EU agency science across sectors is in fact already emerging as a result of both agency practice and legislative reform, rendering the traditional passive approach based on the Access Regulation even more outdated and in need of reform. Such an approach is needed to address the current challenges in the field of risk regulation and crisis management. There are several institutional developments that, while remaining imperfect, point in this direction.[160] Most importantly, the proactive transparency model of the recently reformed GFL[161] offers an inspiration. It provides a suitably balanced and workable legislative solution that could be applied to other agencies, thereby both harmonizing and strengthening access rights for both environmental and health-related information. To give just one example, extending the requirement that information must harm commercial interests "to a significant degree"[162] would make it harder for agencies to refuse disclosure while nonetheless ensuring commercial interests are protected where appropriate.

This shift towards proactive transparency in EU legislation and agency practice stands in strong contrast to the ECJ's case law on access to documents in administrative proceedings, and in particular with the creation of general presumptions. The ECJ's distinct treatment of legislative versus administrative transparency[163] has been widely criticized.[164] It is in tension with the aim of the Access Regulation to "ensure widest possible access to documents".[165] The legal justification for such distinction is dubious at best, given that both the Treaty and the Access Regulation establish openness as a democratic norm underpinning both EU legislation and administration.[166] The ECJ's stance in this regard has been criticized as falling short of transparency as a constitutional norm and as underestimating the general public interest in disclosure in many EU administrative procedures.[167] Neither the Access Regulation nor the Aarhus Regulation differentiate access rights on the basis of the nature of the proceedings governing the submission or drafting of particular documents. Both Regulations, moreover, recognize the link

160. See e.g. the Commission's publicly accessible Register of Commission Documents, available at <ec.europa.eu/transparency/documents-register/>, and its Transparency Register, available at <ec.europa.eu/transparencyregister/public/homePage.do>.

161. See *supra* section 4.

162. Art. 39(2) GFL.

163. E.g. Case C-139/07 P, *TGI*.

164. See Curtin and Leino-Sandberg op. cit. *supra* note 12; Leino-Sandberg, op. cit. *supra* note 14; Mendes, op. cit. *supra* note 6.

165. Art. 1(a) Access Regulation.

166. Arts. 15(1) and (3) and 298(1) TFEU which speak about an "open European administration". See also Recital 2 and Art. 2 (3) Access Regulation

167. Curtin and Leino-Sandberg, op. cit. *supra* note 12; Mendes, op. cit. *supra* note 6.

between transparency and democratic principles. Admittedly, this does not rule out the relevance of functional arguments, which always play a role in the application of legal principles, requiring the weighing of the latter's goals against concerns about the good functioning of EU institutions and procedures. Yet, given the principle of "widest possible access" and the requirement to interpret exceptions strictly, the shielding of administrative procedures from access to documents must not happen across the board. Rather, it should be confined to carefully circumscribed situations, such as those where sectoral rules protect access to the file.[168] We have shown that in the context of risk regulation, the functioning of risk regulatory procedures would actually be undermined by too much secrecy, given the crucial link between transparency and public trust.

Another related feature of EU risk regulation supports this argument. Risk regulation often entails general rule-making of high salience for health and the environment on a broad scale. The qualitative and quantitative bulk of EU risk regulation takes place through administrative implementation. The technical aspects of legislation are specified by the Commission, assisted by a network of EU regulatory agencies.[169] Despite appearances, the implementation phase is not merely about technicalities: EU legislation is often formulated in an open-ended way,[170] and the definition of substantive, often contentious issues, is frequently allocated to non-legislative acts. Recent episodes of politicization of pesticide and GMO authorizations show that, notwithstanding implementation's lower political salience, stakes remain high.[171]Authorization and registration procedures for risk-entailing products concern the allocation of health and environmental risks in society, and involve risk-benefit analysis, as in the case of medicines authorizations, as recently illustrated by the COVID-19 vaccine authorizations by the EMA. The outcome of these procedures are mostly acts of general application: when a substance is approved to be included in a positive list, for example, it can be sold, bought, and used in the manufacture of products throughout the EU. This brings risk regulatory procedures closer to legislative procedures. Therefore, the ECJ's reasoning in the context of legislative proceedings, namely the need

168. See Mendes, op. cit. *supra* note 6.

169. See Art. 291(2) and (3) TFEU.

170. E.g. Art. 1(3) of the Pesticides Regulation: "the purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production". See also Art. 5 GFL.

171. Tosun and Varone, "Politicizing the use of glyphosate in Europe: Comparing policy issue linkage across advocacy organizations and countries", 23 *Journal of Comparative Policy Analysis* (2021), 607–624.

for openness and for citizens "to scrutinize the information and attempt to influence the process"[172] should apply equally to administrative procedures of general rule-making in risk regulation.

5.2. *Transparency and expert accountability*

In this section, we consider the above arguments in favour of a more proactive approach from the perspective of political epistemology, namely the body of interdisciplinary research[173] on the role of experts in modern democracies, and especially in public regulation. Broadly conceived, this body of literature studies both the epistemic and democratic challenges arising from the use of specialized expertise in public decision-making.[174] On the one hand, it recognizes the crucial function of specialized expertise, namely, to maintain the "truth-sensitivity" and problem-solving potential of modern democracies and to regulate effectively. This function in turn relies on the epistemic quality of such expertise.[175] On the other hand, we are facing the dilemma that such epistemic quality cannot simply be ensured through black-box peer-review processes, although these remain crucial. The reasons for that – the social embeddedness of science and its being enmeshed in social and political structures and purposes – have been widely discussed.[176] It is recognized that regulatory science, i.e. scientific knowledge that is produced and used for the purposes of public regulation, constitutes a special type of authority different from other types of epistemic authorities (e.g. research science). It gains political authority as its interpretations and factual assessments are validated by political decisions. As Holger Strassheim points out, the authority of regulatory science lies at the nexus of political and epistemic authority.[177] The authority of regulatory science, therefore, relies on more than peer-review accountability, requiring additional mechanisms of public accountability.

Therefore, a notion of expert accountability has developed that goes beyond processes of expert peer review characteristic for any scientific process, whereby the quality of the scientific work is ensured within closed epistemic

172. Case C-57/16 P, *ClientEarth*, para 92.

173. Including political sociology, political epistemology, studies of regulation and governance, science and technology studies as well as law; see references op. cit. *supra* notes 1 and 2; also Curtin "Challenging executive dominance in European democracy", 77 *The Modern Law Review* (2014), 1–32; Busuioc, *European Agencies: Law and Practices of Accountability* (OUP, 2013).

174. See Holst and Molander op. cit. *supra* note 1 for a good overview of both types of challenges.

175. Ibid.

176. See e.g. Arcuri op. cit. *supra* note 1; Jasanoff op. cit. *supra* note 6.

177. Strassheim, "Behavioural expertise and regulatory power in Europe" in Weimer and de Ruijter op. cit. *supra* note 1, at p. 146.

communities, by subjecting it to scrutiny by peers possessing the same kind of specialized expertise as the experts whose work is being reviewed. Instead, expert accountability obligations are being extended from peer accountability to public accountability, i.e. to *an obligation to explain and justify expert judgements to public fora*.

> "In a process of democratic decision-making, the testing of judgements and arguments must also be extended for epistemic reasons to other relevant disciplines and other relevant expert fora, for example, to fora comprising bureaucrats and competent stakeholders, to the legislature and even to the public sphere at large. In all these fora, experts can be asked to account for critical assumptions, explain models used, specify their limits and present alternative models."[178]

Transparency of science advice is a crucial prerequisite for this kind of broadly conceived expert accountability.[179] It allows scientific advisors to be held to account for the way in which scientific knowledge has been put together in public regulation. It enables agencies to explain and justify the way in which they have used their epistemic discretion, allows for public scrutiny of scientific information and the provision of available counter-expertise. The latter can come from other independent scientists and expert bodies outside the agency, but also from affected stakeholders and laypersons.[180] We should note that transparency and expert accountability here contribute to addressing both the democratic and epistemic concerns around the so-called "expertization"[181] of public decision-making. They contribute to practices of public justification which are seen as improving the deliberative quality of science-based regulatory decisions, which in turn addresses both the epistemic (e.g. cognitive bias, hidden value judgements, capture by special interests) and the democratic (e.g. citizen exclusion, public alienation, depoliticization) concerns around the use of specialized expertise in public

178. Holst and Molander op. cit. *supra* note 1, at 242.

179. On the role of transparency in improving the democratic accountability, good governance and the legitimacy of EU agencies see Bovens, "Analysing and assessing accountability: A conceptual framework", 13 ELJ (2007), 447–468, 462–463; Busuioc, "Accountability, control and independence: The case of European agencies", 15 ELJ (2009), 599–615 and Busuioc, op. cit. *supra* note 173; Schmidt, "Democracy and legitimacy in the European Union revisited: Input, output and 'throughput'", 61 *Political Studies* (2013), 2–22.

180. On the importance of hearing patients' testimonies, see Wood, "Can independent regulatory agencies mend Europe's democracy? The case of the European Medicines Agency's public hearing on Valproate", (2021) *The British Journal of Politics and International Relations*, published online in Nov. 2021, <journals.sagepub.com/doi/full/10.1177/1369148 1211054319>.

181. Holst and Molander op. cit. *supra* note 1.

decision-making.[182] As one of the institutional mechanisms of expert accountability, transparency therefore enables expert decision-making to reconcile the "independence requirement of reliable expertise and the responsiveness requirement of democratic governance".[183]

Having said that, given the urgency of today's health and environmental crises, we would like to emphasize the epistemic function of transparency, i.e. its contribution to holding regulatory experts to account for the epistemic quality of their scientific judgements, which in turn is crucial for the effectiveness of public regulation. A particular concern is the risk of cognitive error and bias in the production of regulatory science. Studies show that experts can make cognitive errors, are prone to overconfidence, and can suffer from cognitive or ideological bias.[184] In fact, scientific experts have been shown to suffer from the same biases as laypeople and moreover show "a strong affiliation bias, with those experts working in industry having a more benign view of the relevant risks that those experts working outside it".[185]

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

> "It seems to me that one principal source of domination of and parochialism in science is domination by class or ethnic interests. The reason for this is based in the simple facts of cognitive bias. Those facts suggest that beliefs and science can easily come to reflect the narrow backgrounds and interests of those who produce them. So, if science and expertise are funded by one particular group in the society there is a significant danger that that expertise will reflect the interests and backgrounds of those persons."[186]

EU risk regulation is not immune to such concerns, as the industry applicants fund and provide most of the evidence on the basis of which market

182. Ibid.; Christiano, "Rational deliberation among experts and citizens" in Parkinson and Mansbridge (Eds.), *Deliberative Systems: Deliberative Democracy at the Large Scale* (Cambridge University Press, 2012); Holst and Molander, "Epistemic worries about economic expertise" in Bátora and Fossum (Eds.), *Towards a Segmented European Political Order: The European Union's Post-Crises Conundrum* (Routledge, 2019).

183. Krick and Holst, "The socio-political ties of expert bodies. How to reconcile the independence requirement of reliable expertise and the responsiveness requirement of democratic governance", 20 *European Politics and Society* (2019), 117–131.

184. Holst and Molander, op. cit. *supra* note 1.

185. Neil, Malmfors and Slovic, "Intuitive toxicology: Expert and lay judgments of chemical risk", 22 *Toxicologic Pathology* (1994), 198–201.

186. Christiano, op. cit. *supra* note 182, at p. 49.

authorizations are granted. The scientific boards of EU agencies, composed of specialized experts, review such evidence and are supposed to do so in an independent way, considering other scientific sources. However, there are ongoing concerns about both the independence and quality of agency assessments, which moreover take place within often underfunded institutions.[187] Such concerns relate, for example, to the risk of selective use or omission of published scientific literature by risk assessors,[188] of risk assessors copy-pasting industry studies in their reports without specifying their origin,[189] to the phenomenon of revolving doors in EU agencies, and conflicts of interests more generally.[190] These concerns should not prompt us to question EU agency assessments in general. But they point to the challenge of ensuring the unbiased nature of the specific type of authority they exert, as well as to the importance of transparency in uncovering potential errors and biases.

Against this background, at least in the field of risk regulation, these insights add to the critique of the passive approach, which is demanding on those seeking access, and gives EU institutions a wide discretion in applying exceptions. It also adds to the critique of the ECJ's approach to general presumptions and its treatment of administrative transparency as "second best" as compared to legislative transparency. The ECJ's understanding of administrative decision-making as being a technical, low-politics exercise, in which openness as a democratic value is of little salience seems outdated and should be rethought.

6. Conclusion

The main finding of this article is that the current legal approach to the transparency of EU agency science is undergoing significant change as a result of new legislation and agency practice. The traditional "passive" approach based on access rights under the EU Access Regulation and applicable sectoral legislation suffers from several shortcomings; it is

187. See Robinson et al., op. cit. *supra* note 70. See also the European Parliament Report on the Union's authorization procedure for pesticides, 18 Dec. 2008, available at <www.europarl.europa.eu/doceo/document/A-8-2018-0475_EN.html>.

188. Pesticide Action Network Europe and Générations Futures, "Missed and Dismissed", Pesticide Action Network Europe, 2014, available at <www.pan-europe.info/old/Resources/Reports/PANE%20-%202014%20-%20Missed%20and%20dismissed.pdf>.

189. As happened in the 2017 reauthorization of glyphosate, where the German Federal Institute for Risk Assessment had copied text from the industry application; see EP Report cited *supra* note 187.

190. Robinson et al., "Conflicts of interest at the European Food Safety Authority erode public confidence", 67 *Journal of Epidemiology and Community Health* (2013), 717–720.

fragmented and outdated. Our findings call for both legislative reform and judicial rethinking. First, the analysis of the case law of the EU Courts on the use of general presumptions in risk regulation has shown the problematic distinction between legislative and administrative transparency, which is not adequate in this field, in which administrative rule-making impacts broadly on people's health and the environment. While so far no general presumptions have been established in risk regulation, recent problematic trends were highlighted in the case law, which if continued could increase administrative secrecy around EU agency science. Second, it was shown that the wide interpretation of the Aarhus Regulation in recent case law makes it a powerful tool in extending access to environmental information held by commercial actors. At the same time, the Regulation re-enforces administrative secrecy. Moreover, at a time of growing awareness of the intertwinement between health and environmental risks, new instruments are needed to ensure high standards of transparency not only for environmental, but also for health-related information. Third, the analysis of the EU legal framework for access to documents held by the three EU risk regulation agencies, the EMA, ECHA and EFSA, has shown that the patchwork of general and sectoral provisions creates legal fragmentation, which leads to variations in the way in which access rights are given effect across the agencies. While the EMA and EFSA have moved to a "proactive" approach based on early publication of all relevant scientific information, the ECHA falls below even the standards of the "passive" approach based on the Access Regulation. The current situation is difficult to justify both on normative and functional grounds. It is also in tension with insights from interdisciplinary research, which emphasizes the crucial role of transparency of agency science in publicly holding regulatory science to account. We welcome the emergence of a new "proactive" approach to transparency, as embraced by, among other developments, the amended EU General Food Law, as a more promising model to address current and future challenges of EU risk regulation. This approach should be extended to the legal frameworks governing other EU risk regulation agencies. It also offers inspiration for the future rethinking of the meaning and purpose of transparency under the EU Access Regulation. In particular, it can help counter the trend towards more administrative secrecy in EU law, as well as reset the balance of rights and interests in favour of the principle of widest possible access.