The Transparency of EU Agency Science – Towards a new proactive approach post-Covid19

Hickey, E.; Weimer, M.

DOI
10.2139/ssrn.3962175

Publication date
2021

Document Version
Final published version

UNIVERSITY OF AMSTERDAM

AMSTERDAM CENTRE FOR EUROPEAN LAW AND GOVERNANCE

THE TRANSPARENCY OF EU AGENCY SCIENCE – TOWARDS A NEW PROACTIVE APPROACH POST-COVID19

Eógan Hickey

Maria Weimer

Amsterdam Law School Legal Studies Research Paper No. 2021-38

Amsterdam Centre for European Law and Governance Research Paper No. 2021-04

The Transparency of EU Agency Science –

Towards a new proactive approach post-Covid19

Eógan Hickey and Maria Weimer

Abstract:

There is broad agreement about the normative value of transparency when it comes to agency science, i.e. the scientific information that underpins, and often significantly shapes, public regulation. Transparency of agency science is seen as crucial in securing the legitimacy of and trust in EU risk regulation. Yet, how exactly transparent scientific advice for policy should look like in practice and what role law plays in this regard is much more disputed. In this paper, we analyse recent EU legal and regulatory developments concerning access to information held by the three most important risk regulation agencies, the European Medicines Agency, the European Food Safety Authority, and the European Chemicals Agency. Our main finding is that the current EU legal approach to the transparency of agency science is undergoing significant change as a result of both legislative change, agency practice and recent developments of Covid19 pandemic management. The traditional 'passive' approach based on access rights under the EU Access Regulation is fragmented, and suffers from several shortcomings which require urgent legislative reform as well as judicial rethinking. Recent trends, such as the 2021 reform of the EU General Food Law, indicate that the EU is moving towards a new approach of 'proactive transparency,' which is better suited to address the challenges of risk regulation and crisis management.

Introduction

The transparency of EU regulatory science[1] – that is of the scientific information held by EU agencies – has been the subject of a wide-ranging academic and policy debate. Transparency in regulation can broadly be defined as 'the conduct of [regulation] in a fashion that makes decisions, rules and other information visible from the outside.'[2] On the one hand, the normative value of transparency is largely undisputed. Legally, there is a constitutional commitment to open decision-making in both the Treaty[3] and EU secondary legislation, which extends to EU agency science. There is also broad agreement among scholars, stakeholders and policy makers on the normative goals which transparency is expected to achieve in this field.[4] The transparency of regulatory science is seen as instrumental in enhancing public trust in agency decision-making and risk regulation more broadly. Transparency is also seen as crucial for the accountability of science-based decision-making. It enables public scrutiny, which in turn helps enhancing the epistemic quality as well as the integrity of agency science. Lastly, it also has the potential to empower citizens and to enable their participation in public decision-making.

[1] The 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* (HUP, 1995) and Jasanoff, "Quality control and peer review in advisory science" in: J Lentsch and P Weingart (Eds.): The Politics of Scientific Advice. Institutional Design for Quality Assurance (CUP, 2011), 19-35.

[2] Hood, 'Accountability and transparency: Siamese twins, matching parts, awkward couple?' *West European Politics*, (2010) 33(5), 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.

[3] Art. 10 (3) TEU, Art. 11 (2) TEU, Art. 15 (3) TFEU ; see Alemanno, 'Unpacking the principle of openness in EU law: transparency, participation and democracy' 39(1) EL Rev. (2014), 72-90; Prechal and De Leeuw, 'Dimensions of Transparency: The Building Blocks for a new Legal Principle?' 1(1) REALaw (2007), 51-62, 51-62. See Way et al., ibid.

In these different yet related ways, transparency is understood as contributing to the legitimacy of EU agencies and their decision-making.[5]

Yet, how exactly transparent scientific advice for policy should look like to achieve these goals in practice is much more disputed. The currently dominant EU legal approach is one of 'passive transparency' based on the EU Access Regulation,[6] 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, the granting of the right to access requires balancing between the public interest of access and the need for confidentiality to protect competing interests, in the case of risk regulation above all as the commercial interests of the regulated industry and the administrative process respectively. Recent regulatory controversies have highlighted shortcomings in the operation of this legal regime when applied to EU agencies.

The controversial EU reauthorisation of glyphosate in 2017, the active substance in Bayer/Monsanto's Roundup and the world's most widely used herbicide, is a case in point. The substance was previously classified as probably carcinogenic to humans by the International Agency for Research on Cancer (IARC). In the US, massive litigation for damages brought by cancer victims against Monsanto has brought to light the so-called 'Monsanto papers,' which revealed problematic practices by the company aiming to downplay the risks associated with glyphosate.[7] At the same time, the EU risk assessment of glyphosate carried out by two EU agencies, the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), heavily relied on the scientific data and other information provided by the industry applicants. The agencies' green light for glyphosate led to a (renewed) marketing approval by the Commission. The latter was in turn hotly debated raising concerns over the independence of EU agency science, the role of the regulated industry in the authorisation procedure, and triggering public distrust in EU pesticides regulation,[8] a special parliamentary inquiry and EU legislative action.[9] Importantly, attempts to gain full access and scrutinize the scientific information underlying the risk assessment of glyphosate have remained largely unsuccessful due

[5] See Hood, op. cit. *supra* note 2; Hood and Heald, Transparency: the key to better Governance? 2006; Jasanoff, 'Transparency in Public Science: Purposes, Reasons, Limits', (2006) 69 Law and Contemporary Problems, 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 available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3557795 (last visited 21 June 2021); Holst and Molander, 'Responding to Crises - Worries About Expertization', in Riddervold et al. (Eds.), *The Palgrave Handbook of EU Crises* (Palgrave Macmillan, 2021), 647-665; Schmidt and Wood, 'Conceptualizing Throughput Legitimacy: Procedural Mechanisms of Accountability, Transparency, Inclusiveness and Openness in EU Governance", 97(4) Public Administration (2019), 727-740.

[6] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents

[7] https://usrtk.org/monsanto-papers/; https://corporateeurope.org/en/food-and-agriculture/2018/03/what-monsanto-papers-tell-us-about-corporate-science; e.g. it is claimed that Monsanto has ghost-written scientific articles and intentionally omitted to carry out safety studies.

[8] For a recent study on public opinion on EU pesticides regulation, see Zeitlin et al., *Reforming EU Pesticides Regulation, Rebuilding Public Support: Evidence from Survey Experiments in Six Member States* (June 8, 2021). Amsterdam Centre for European Studies Research Paper No. 2021/03

[9] For a good account of these developments see Arcuri and Hendlin, ' The Chemical Anthropocene: Glyphosate as a Case Study of Pesticide Exposures', King's Law Journal, (2021), (forthcoming, available online at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3413272)

to a strict interpretation of confidentiality rules by the EFSA and leading to a judicial challenge against that agency.[10]

Moreover, recent developments in both EU legislation and the practice of some EU agencies 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 newly reformed EU General Food Law[11] embraces a new approach of 'proactive transparency' for EU risk assessments in the food chain, which no longer depends on access requests. Moreover, the Covid19 crisis has accelerated this trend with several EU institutional actors supporting proactive, early and full publication of all scientific information underlying pandemic management and the authorisation of Covid19 medicines as well as better science communication.

In this contribution we engage with these developments as well as recent CJEU case law on access to EU agency science. Our goal is to analyse the current EU legal framework for access to documents of EU agencies identifying its shortcomings as well as recent trends, including the emergence of a new proactive approach to transparency in this field. While there is a rich legal scholarship on access to documents to and the transparency of EU institutions in general, legal research on the transparency of EU regulatory science has been scarce. Existing studies have shown the crucial role of EU agencies as holders of information that is both commercially sensitive and of high public interest for both regulators and citizens. It has been argued that agency practices and interpretation of transparency rules are often in tension with EU public access legislation and that such practices involve the exercise of political discretion with regard to how conflicting public interests should be arbitrated.[12]

Building on existing insights, our contribution is threefold. Firstly, our analysis includes recent developments that have not yet been comprehensively examined. This includes the 2021 reform of EU General Food Law (the 'GFL'); new EU case law on general presumptions in the field of risk regulation; as well as developments in the context of Covid19 pandemic management. We also shed new light on the role of the Aarhus regulation in ensuring transparent risk regulation by questioning the adequacy of the underlying legislative distinction between environmental and health-related information.

Secondly, looking beyond risk regulation, our analysis contributes to the broader discussion on EU administrative transparency. The main thrust of CJEU case law on access to documents has been to strengthen the transparency of the EU legislative process.[13] In contrast, the Court's track record on the transparency of the EU administrative process is arguably less progressive despite the fact that both the Treaty and the Access Regulation establish openness as a democratic norm underpinning both EU legislation and administration.[14] The Court's stance in this

[10] See Korkea-aho and Leino-Sandberg, 'Who Owns the Information Held by EU Agencies? Weed Killers, Commercially Sensitive Information and Transparent and Participatory Governance', 54(4) CML Rev. (2017), 1059-1091.
[11] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.
[12] Korkea-aho and Leino-Sandberg, ibid. n 10.
[13] See: Joined Cases C-39/05 P and C-52/05 P, *Sweden and Turco v Council* EU:C:2008:374; Case C-280/11 P *Council v Access Info Europe* ECLI:EU:C:2013:671.
[14] Arts. 15 (1) and (3) and 298 (1) TFEU which speak about an 'open European administration.' See also the Access Regulation, Recital 2 and Article 2 (3).

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.[15] The need to improve administrative transparency has been identified as a key challenge to be addressed in EU law on access to documents in the years to come.[16] We examine how this challenge is or should be addressed in the field of EU risk regulation, but also argue that developments in risk regulation can shed new light on the question of how administrative transparency should be treated in EU law.

Finally, we add an external perspective based on insights from interdisciplinary research on the role of transparency in agency legitimacy. We juxtapose current legal approaches to EU agency transparency with a rich body of interdisciplinary research studying the politics and epistemic power of scientific expert bodies, as well as the role of transparency in securing expert accountability and agency legitimacy.

In the following, we begin by analysing what we call the traditional 'passive' approach to transparency and its shortcomings. Section 1 outlines the basic principles of the EU Access Regulation before focusing on recent CJEU case law on general presumptions in the field of EU agencies and risk regulation, and highlighting the problems with both commercial and administrative secrecy in this field. Section 2 discusses the positive impact of the Aarhus Regulation on broad access to environmental information held by EU agencies, yet contrasts that with the lack of a similarly broad access to health-related information. Section 3 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 4 juxtaposes our findings with interdisciplinary insights, which show the importance of 'proactive transparency' for agency legitimacy. At last we conclude.

1. 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.[17] Since the Treaty of Lisbon, transparency is part and parcel of the EU's normative commitments to democratic principles of representative and participatory democracy,[18] 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 citizen.'[19] These constitutional commitments have been given effect, among other, through the codification of the fundamental right of access to documents[20] in Regulation 1049/2001 (Access Regulation) as well as through a longstanding line of CJEU jurisprudence.[21]

---

[15] Curtin and Leino, 'Openness, Transparency and the Right of Access to Documents in the EU' Robert Schuman Centre for Advanced Studies Research Paper No. RSCAS 2016/63 https://cadmus.eui.eu/handle/1814/45327 (last accessed 18 June 2021), p. 23.
[16] Curtin and Leino, ibid.
[17] Koen Lenaerts, 'The Principle of Democracy in the Case Law of the European Court of Justice', 62 ICLQ (2013), 271-315, 277; Prechal and Leeuw, op. cit. *supra* note 3.
[18] Title II TEU, in particular Art. 10.
[19] Art. 10 (3) TEU. On transparency as an element of the principle of openness, Alemanno, op. cit. *supra* note 3.
[20] Art. 42 Charter of Fundamental Rights; see also Art. 15 (3) TFEU.
[21] Lenaerts, op. cit. *supra* note 17.

In this section, we discuss the 'traditional' EU approach to transparency represented by the Access Regulation and its relevance and shortcomings with regard to EU agency science. As usual, the Court's interpretation of the Regulation has significantly shaped this approach. One of the most criticized aspects of the access to documents case law so far has been the creation by the Court 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 the health and environmental protection, this represents a missed opportunity for strengthening public scrutiny and for improving agency legitimacy.

The Access Regulation codifies the right of any Union citizen to obtain access to all documents held by EU institutions 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 directly apply to them. 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 instead governed by a number of sectoral regulations. The latter generally incorporate the provisions and principles of the Access Regulation, albeit with sometimes 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. As a result, the actual meaning of transparency in this field differs depending on the agency and the regulatory approval procedure concerned.

As a starting point, the general legal framework of the Access Regulation aims to ensure 'widest possible access to documents'[22] while also protecting a number of public and private interests thereby achieving an adequate balance between disclosure and confidentiality. Therefore, the principle of widest possible access may be departed from where an exception under Article 4 applies. Two exceptions are particularly relevant when it comes to 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).[23] The 'commercial interests' exception allows institutions to refuse access where disclosure would undermine a natural or legal person's commercial interests. In EU authorisation procedures, such 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[24] 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 is also typically the case in risk regulation procedures given that the agency scientific advice is only an intermediate procedural step towards the final decision taken by other EU institutions, most notably the European Commission.

[22] Art 1(a).
[23] 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)).
[24] Art. 4 (4), Access Regulation.

Restrictions to the right of access based on these exceptions however may be overcome where the person seeking access is able to prove an overriding public interest in disclosure. According to established case law,[25] such exceptions must be interpreted and applied narrowly.[26] However, the Court has seriously tempered 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 of *Sweden and Turco* and then confirmed two years later in *TGI* the CJEU has developed a concept general presumptions of confidentiality.[27] General presumptions are an entirely judicial innovation, having absolutely no basis in the Access Regulation. Essentially, they entitle institutions in certain cases to presume that an exception to access applies, without being obliged to specifically and individually examine whether each of the documents requested falls under that exception. Documents must belong to certain judicially recognised categories of document, the Court reasoning that similar considerations of confidentiality are likely to apply to documents of the same nature.[28] The Court has recognised general presumptions over categories of documents in an array of administrative proceedings, namely state aid,[29] merger control,[30] cartels,[31] infringement proceedings[32] and EU pilot proceedings.[33] The net result of general presumptions is to place a heavy burden of proof on those seeking access, who must then prove an overriding public interest in disclosure of documents they have not had sight of. This has been repeatedly criticised for placing an impossibly high burden of proof on those seeking access, without any basis in legislation or the Treaties.[34]

What is notable about the categories of documents over which general presumptions may apply listed above is that they all belong to proceedings which are administrative in nature. Mendes has argued that general presumptions reflect functionalist concerns of protecting the effectiveness of EU law and integration by guarding Commission prerogatives, in a way that is sometimes at odds with the EU's democratic character.[35] In our observation, when compared with attempts to protect commercial interests or legislative space to think, the Court's case law on general presumptions also demonstrates a privileging of administrative secrecy.

The case law on general presumptions reveals that the Court has a resolute preference for openness in legislative matters which was explicitly recognised in *TGI*, where the court held that 'where the Community institutions act in the capacity of a legislature … wider access to documents should be authorised ….'[36] The Court has accordingly resisted attempts to assert general presumptions of confidentiality over documents in legislative proceedings. For example,

[25] Case C-280/11 P *Council v Access Info Europe* ECLI:EU:C:2013:671, para 30.
[26] Section 3.
[27] Case C-39/05 and C-52/05 P *Sweden and Turco*, op cit *supra* note 13, para 50; Case C-139/07 P *TGI* ECLI:EU:C:2010:376. See: Rossi and Vinagre e Silva, *Public Access to Documents in the EU* (Hart, 2017), 152ff, and Dariusz Adamski, 'Approximating a workable compromise on access to official documents: the 2011 developments in the European Courts', 49(2) CMLR, (2012), 521-558.
[28] *TGI*, ibid, para 54.
[29] *TGI*, Ibid.
[30] C-404/10 P *Éditions Odile Jacob* ECLI:EU:C:2012:393.
[31] C-365/12 P *EnBW Energie Baden-Württemberg AG* ECLI:EU:C:2014:112.
[32] C-605/11 P *LPN and Finland v Commission* EU:C:2013:738.
[33] C-562/14 P *Sweden v Commission* ECLI:EU:C:2017:356.
[34] Adamski, op. cit. *supra* note 27, 526; Curtin and Leino, op. cit. *supra* note 15; Craig, *EU Administrative Law* (2nd Ed, OUP, 2012), 363; and Mendes, op. cit. *supra* note 5, 13-14 and 16-17.
[35] Mendes, op. cit. *supra* note 5.
[36] *TGI*, *supra* note 27, para 60. See generally Adamski, op. cit. *supra* note 27.

in *ClientEarth v Commission*,[37] the Court refused to recognise a general presumption over impact assessments and related documents (some of them draft) intended to assist the Commission in drawing up legislative proposals.[38] It held that such documents form 'part of the basis for the legislative action of the European Union'[39] and strongly emphasised democratic principles, stating that disclosure of the documents would increase transparency and openness of the legislative process, allowing citizens to scrutinise the information and attempt to influence the process.[40]

1.1. General presumptions to protect the administrative space to think

In the domain of risk regulation, the Court has not yet definitively considered whether the EFSA, EMA or ECHA may apply general presumptions to protect their space to think in authorisation procedures. Some initial case law suggested that they may not. In *Borax* the General Court 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, despite concerns experts might be deterred from giving opinions in future.[41] However, we should avoid placing much reliance on this judgment because general presumptions were at that point in their absolute 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.

On one hand, more recently the Court has signalled willingness to allowing risk regulation agencies to invoke general presumptions to protect their space to think. In *MSD* the General Court left open the possibility that a general presumption of non-disclosure can apply in authorisation procedures so long as a decision-making process was ongoing, in order to protect the agency's space to think,[42] acknowledging 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 jeopardised.'[43] This includes where intervention of third parties risks undermining the procedure.[44] However, those statements were *obiter* as the procedure in *MSD* had concluded and on appeal the ECJ did not deal with this point.[45]

On the other hand, however, the Court has also recently begun to recognise the importance of openness and democracy in agency scientific decision-making. In *Tweedale*, *Hautala*, *PTC* and *MSD* the Court gave cursory acknowledgment to the role of openness which 'enables the EU institutions to have greater legitimacy and to be more effective and more accountable to EU

[37] C-57/16 P *ClientEarth v Commission* ECLI:EU:C:2018:660.
[38] Para 109, 112. The Court 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 Court 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).
[39] Para 91.
[40] Para 92, 108.
[41] Case T-121/05 *Borax Europe* ECLI:EU:T:2009:64, para 67-71. The Court rejected the Commission's arguments that disclosure presented a risk to the process as being general and abstract and held the Commission was obliged to specify how disclosure would concretely and effectively undermine the process.
[42] Case T-729/15 *MSD* ECLI:EU:T:2018:67, ('*MSD*, GC'), para 26, 27 and 32.
[43] Ibid, para 26.
[44] Ibid.
[45] Case C-178/18 P *MSD* ECLI:EU:C:2020:24, ('*MSD*, ECJ'). 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', EJRR, first view April 2021.

citizens in a democratic system ….'[46] However, whether this statement will have any real consequences for access to documents in risk regulation remains to be seen. For the moment, demonstrating the Court's preference for legislative openness, concerns for democracy and openness remain far more pervasive in cases pertaining to legislative documents than in any of these cases.[47] Moreover, although disclosure was made in *Tweedale* and *Hautala*, these cases concerned access to environmental information under the Aarhus Regulation (considered in the next section) to which special concerns of transparency apply. Likewise, *MSD* and *PTC* concerned commercial interests rather than space to think (although the litigant companies erroneously sought to invoke the latter exception).

What is clear is that general presumptions may already be invoked to protect administrative space to think in a host of areas, but never in legislative proceedings. In light of the General Court's comments in *MSD,* if agencies can convince the Court 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 authorisation proceedings.

When compared to its preference for legislative openness, this privileging of administrative secrecy would be hard to justify if extended to risk regulation. While, strictly speaking, authorisation proceedings are administrative in nature, special concerns apply in the field of risk regulation which merit increased transparency. For reasons discussed in the last section of this paper, transparency is central to agency legitimacy. Though administrative in nature, a grant of authorisation 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 authorisation decisions are unlike many other kinds of administrative decisions. Recent controversies around the re-authorisation of glyphosate serve as a case in point. While citizens and civil society organizations have the opportunity to examine documents over which Article 4(3) of Access Regulation was asserted once the authorisation procedure has 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[48] could actually be undermined, if agency opaqueness contributes to citizens no longer trusting agency decisions, as the glyphosate controversy demonstrates. Accordingly, there is a strong case for extending the Court's high standards of legislative transparency to the field of risk regulation. At a minimum, the Court should refuse to allow agencies to invoke a general presumption that disclosure of documents before the authorisation process is concluded would undermine its 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 authorisation application as adopted under the new GFL.[49]

---

[46] Case T-716/14 *Tweedale* ECLI:EU:T:2019:141, para 54; T-329/17 *Hautala* ECLI:EU:T:2019:142, para 60; C-175/18 P, *PTC Therapeutics International v EMA* ECLI:EU:C:2019:709, para 53; *MSD*, ECJ, *supra* note 45, 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(2) EJRR (2019) 419-427.

[47] See for example *Sweden and Turco*, *supra* note 13, paras 34, 45-46, 59, 65-67.

[48] See Mendes, op. cit. *supra* note 5.

[49] See section 3.

1.2. General presumptions to protect commercial interests

The differentiation in access rights resulting from general presumptions does not stop here, however. The Court's privileging of administrative secrecy is also visible when we compare its treatment of administrative interests with its treatment of commercial interests. While the Court 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 authorisation holders' commercial interests, although the point is, as we discuss further below,[50] somewhat uncertain. Commercial interests are particularly salient in risk regulation. As part of the authorisation process, industry applicants submit dossiers of data which are assessed by the agency, much of which 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% of all access requests received by EFSA came from industry, down from 71% in 2018.[51] This presents a potential threat to applicants' commercial interests, who fear that commercially sensitive information will be disclosed.

Moreover, the Court has repeatedly stated that in all cases where it has found a general presumption, the documents were clearly defined by the fact they related to ongoing administrative or judicial proceedings,[52] thus clearly referencing space to think. Whether this actually amounts to a criterion for recognising a general presumption was recently contested by AG Hogan in *PTC* and *MSD*, who proposed a broad and versatile test that would have permitted a general presumption wherever it was reasonably foreseeable that disclosure of a category of documents would be liable to undermine *any* protected interest (including commercial).[53] Although the Court in *PTC* and *MSD* declined to clarify whether general presumptions can protect commercial interests, the fact remains that according to the Court itself, all proceedings in which a general presumption has been recognised were administrative or judicial in nature. If this is not a criterion, it is difficult to understand why the Court keeps restating it. It is also worth noting that the judgment from which AG Hogan drew this broader supposed test, *ClientEarth*, itself reiterated this statement – something the AG did not mention.[54] Moreover, *ClientEarth* concerned an ongoing procedure and did not concern protection of commercial interests. In any case, even if the test proposed by AG Hogan is the correct one,[55] the Court has yet to recognise a general presumption in favour of parties' commercial interests, but has recognised general presumptions to protect administrative interests in a host of areas.

[50] See section 3.
[51] ECHA, 'ACCESS TO DOCUMENTS AT ECHA – 2019 KEY FIGURES' https://echa.europa.eu/documents/10162/13604/atd_2019-key-figures_en.pdf/195abe9f-b4aa-d729-a2a3-d05191edd144 (accessed 3 April 2021); ECHA, 'ACCESS TO DOCUMENTS AT ECHA – 2020 KEY FIGURES' https://poisoncentres.echa.europa.eu/documents/10162/13604/atd_2020-key-figures_en.pdf/28f961d7-1a20-1448-9539-33dac30b83d0; ECHA, ' Access to documents at ECHA – 2018 Key figures' https://echa.europa.eu/documents/10162/13604/adt_2018-key-figures_en.pdf/686ca66d-a5f9-ed9c-604e-0c696e44a7b3 (accessed 3 April 2021). See also Mendes, op. cit. *supra* note 5, (p 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?' European Political Science Review, Vol 12 (3), pp. 347-369.
[52] *Sweden v Commission*, *supra* note 33, para 44; *ClientEarth v Commission*, *supra* note 37.
[53] Opinions of AG Hogan in *PTC*, ECLI:EU:C:2019:709, para 70 and *MSD*, ECJ, *ECLI*:EU:C:2019:710, para 50.
[54] *ClientEarth v Commission*, *supra* note 37, para 62.
[55] See also: Hickey, op. cit. *supra* note 45.

If the Court were to recognise general presumptions to cover commercial interests, this would be very problematic in risk regulation. There are already concerns about the reliability of scientific information submitted by applicant companies.[56] General presumptions in favour of companies' commercial interests would seriously undermine public scrutiny of information submitted as part of the application process, because in many ways the commercial interests exception is a stronger exception than the space to think one. The latter is inherently time limited and 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 authorisation 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) to apply. 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 be 'undermined.'[57] 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.

2. 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 further strengthening access rights with regard to environmental information. It also further demonstrates the privilege accorded to administrative secrecy, in large part because it mandates absolute standards of openness where commercial confidentiality is asserted over certain environmental information, but not where other exceptions are asserted.

The Aarhus Regulation was enacted to meet the Union's obligations under international law, namely the Aarhus Convention.[58] 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'[59] and therefore includes the agencies. It *inter alia* guarantees the public's right of access to environmental information received or produced by EU Institutions or bodies,[60] and ensures institutions and bodies actively disseminate certain environmental information.[61] 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 CJEU has given a very generous interpretation to the meaning of 'emissions into the environment.' In *Greenpeace v Commission (Glyphosate)*[62] it held that Article 6(1) of the Aarhus

[56] See: Robinson et al., op. cit. *supra* note 86.
[57] This was confirmed by the Court in *PTC, supra* note 92, para 90.
[58] 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) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (the 'Aarhus Regulation').
[59] Arts. 1(a), 3, Aarhus Regulation.
[60] Aarhus Regulation, Art. 1(a).
[61] Aarhus Regulation, Art. 1(b).
[62] Case C-673/13 *Greenpeace* ECLI:EU:C:2016:889.

Regulation was to be given the broadest possible meaning in accordance with the principle of widest possible access to documents.[63] 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 accordingly held that 'emissions' could include emissions of pesticides into the environment. [64] It moreover concluded that 'emissions into the environment' is not limited to information relating to *actual emissions* but may also cover information relating to *foreseeable emissions*.[65] 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 authorisation and which prevail in the area of intended use.[66]

In *Bayer CropScience*,[67] which it delivered on the same day, the Court 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.'[68] It recently 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].'[69]

This was affirmed and bolstered by the General Court in *Hautala*[70] and *Tweedale.*[71] There, the applicants sought access to studies used by EFSA to assess the carcinogenicity of glyphosate in its controversial decision to reapprove the substance. In both cases, 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. 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.[72]

The General Court reiterated that emissions into the environment include information relating to those emissions' effects.[73] It emphasised 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.[74] It accordingly found an overriding public interest in disclosure.[75] It rejected as irrelevant the argument that the raw data was sufficient to allow the public to verify results.[76] The Court confirmed that protection of commercial interests could not prevent disclosure of information relating to emissions into the environment under Aarhus.[77]

The net effect of Article 6(1) and its interpretation by the CJEU 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

[63] *Greenpeace*, ibid, para 50–55.
[64] *Greenpeace*, Ibid, para 62
[65] *Greenpeace, ibid* paras 71–76.
[66] Ibid, para 75.
[67] Case C-442/14 *Bayer Cropscience* ECLI:EU:C:2016:890.
[68] *Bayer Cropscience,* ibid., para 96.
[69] Case C-616/17 *Blaise* ECLI:EU:C:2019:800, para 108.
[70] *Hautala*, *supra* note 92.
[71] *Tweedale*, *supra* note 92.
[72] *Hautala, supra* note 92, paras 23 – 24.
[73] *Hautala, ibid,* paras 99, 106
[74] *Hautala, ibid,* paras 121, 97.
[75] *Hautala, ibid,* paras 122, 123.
[76] *Tweedale, supra* note 92, para 121.
[77] *Tweedale, ibid,* paras 126-128.

exception, Article 6(1) always deems an overriding public interest to apply,[78] essentially creating an irrefutable right of access.

Yet, Article 6(1) is less helpful to applicants where an agency asserts that disclosure would jeopardise its space to think, even where information relates to emissions, which once more confirms the privilege of administrative secrecy, this time as a result of legislative drafting. 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.[79]

In *ClientEarth v Commission*, albeit in a legislative context, the Court of Justice overturned the General Court'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 Court invoked the second sentence of Article 6(1) to conclude that exceptions must be interpreted strictly where the request concerns environmental information.[80] There is no basis in the Aarhus Regulation to treat administrative documents differently to legislative ones,[81] and those of us who favour greater agency openness would hope that the commitment under Article 6(1) to interpret exceptions restrictively, combined with the Court's recent recognition of openness and participatory democracy in agency proceedings,[82] will protect the right of access to environmental information held by agencies from such hazards as general presumptions of confidentiality. Yet, we should also not forget that the general requirement to interpret exceptions to access restrictively has not stopped the Court from recognising general presumptions in other areas. Indeed, there is similarly no basis in the Access Regulation for treating legislative documents differently to administrative ones, but the Court 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, for example, space to think is asserted.

Aarhus represents 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'[83] can only stretch so far, despite the Court'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

[78] See: Rossi and Vinagre e Silva, op. cit. *supra* note 73, 171.
[79] See: Rossi and Vinagre e Silva, ibid, 171.
[80] *ClientEarth v Commission*, *supra* note 83, para 100.
[81] However in *ClientEarth v Commission,* ibid, in addition to Art. 6 of the Aarhus Regulation the Court also relied heavily on the increased importance of access to documents in the legislative process. See para 85-95, 105.
[82] *Tweedale*, *supra* note 92, para 54; *Hautala*, *supra* note 92, para 60; *MSD*, ECJ, *supra* note 91, para 50; PTC, *supra* note 92, para 53. See: Morvillo, op. cit. *supra* note 92.
[83] See definition under Art. 2(1)(d), Aarhus Regulation.

definition. Yet, the authorisation 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 obviously not to criticise the strengthening of access rights under the Aarhus Regulation. Rather it is to 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 Court's already-signalled openness to recognising general presumptions in authorisation proceedings greatly increase the difficulty of obtaining such information.[84]

3. 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 next. 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 ECHA, EMA and EFSA. The scientific advice provided by these agencies is often decisive for the authorisation of risk-entailing products and substances on the EU internal market. Therefore, questions of independence, epistemic quality and transparency[85] of the underlying scientific information are often at the forefront of debates and controversies surrounding the work of these agencies.[86]

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 actually set higher standards of openness than does 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[87] not foreseen in the Access Regulation by defining certain types of information that is *deemed* to be commercially confidential and therefore justifies the denial of access. In the case of ECHA, both the Biocides Regulation and the REACH Regulation provide such modified exceptions for the protection of commercial interests.[88] On the one hand, in *ClientEarth and ICS* the General Court accepted that Article 118 of REACH created a general presumption

[84] As discussed earlier - *MSD*

[85] The scientific risk assessment carried out by EU agencies must therefore be excellent, independent and transparent, see Case T-13/99 *Pfizer Animal Health* ECLI:EU:T:2002:209, para. 159.

[86] For example 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) https://www.bbc.com/news/world-europe-18007004 (last accessed 18 June 2021); see also Claire Robinson et al, 'Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions', 11(3) EJRR (2020), 450-480.

[87] On general presumptions see below section 2.

[88] Art 66(2) Biocides Regulation and Art 118(2) REACH.

that disclosure of precise tonnage would undermine the authorisation holders' commercial interests.[89] Yet on the other hand, it later took the opposite position in *Deza*.[90] Accordingly, in *Deza* it held that the ECHA was obliged to specifically and individually examine each document to consider whether it was covered by the exception.[91] Thus, whether *Deza* can be considered as overruling *ClientEarth and ICS* remains unclear, not least because the Court in *Deza* did not refer to *ClientEarth and ICS*.[92] As already discussed above,[93] general presumptions of confidentiality in risk regulation, therefore, remain a distinct possibility pending further clarification by the Court.

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.'[94] ECHA's internal policy on access to documents similarly makes no mention of overriding public interests.[95] 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.[96] Second, the words 'may disclose' in REACH indicates that disclosure in urgent situations is entirely discretionary on the part of 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 does not fully convince 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. It is hard to see why, for example, information as to precise tonnage or links between manufacturers and distributors in relation to one product should ordinarily be considered confidential because it has applied for a marketing authorisation under the Biocides Regulation, but the same presumptions should not apply to other substances. 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 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

[89] Case T-245/11 *ClientEarth and ICS v ECHA* ECLI:EU:T:2015:675, para 173–175.
[90] Case T-189/14 *Deza v ECHA* ECLI:EU:T:2017:4, para 38–40.
[91] *Deza*, ibid, para 41-42.
[92] See: Korkea-aho and Leino, op. cit. *supra* note 10, 1079.
[93] Section 1.
[94] REACH Art 118(2), final paragraph.
[95] ECHA, 'Decision on the Implementation of Regulation 1049/2001", MB/12/2008 adopted 25 March 2009 https://echa.europa.eu/documents/10162/13604/mb_12_2008_final_implementing_rules_access_to_documents_en.pdf/8b081a88-4e70-447c-a069-13d953f47948 (accessed 7 April 2021)
[96] See: Korkea-aho and Leino, op. cit. *supra* note 10, 1070.

a separate 'throw of the dice' to lobby the EU legislature to roll back transparency requirements.[97] Where certain industries are more effective at lobbying than others this may create divergent rights of access.[98]

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 Regulation applies to documents held by the agency and requires the Management Board to adopt measures implementing the Regulation.[99] Following a recommendation of the European Ombudsman,[100] the EMA has also adopted a very robust policy of proactive publication and dissemination of clinical data.[101] 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.[102]

However, 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 with regard to agency science. The pre-amendment GFL 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 the Board did in its 2003 Decision on Access to Documents.[103] 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 authorisation procedure in question. Some such regulations failed to provide that they were governed by the principles of the Access Regulation.[104] Others only did

[97] For example, in its first reading of Regulation 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (the "Pesticides Regulation"), 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 October 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 October 2007, 23, comments of Erna Hennicot-Schoepges; and Debates of the European Parliament, 23 October 2007, 43, comments of Carl Schlyter.

[98] On the influence of lobbying in the EU see Dür & ors 'Lobbying and business success in different policy areas: REACH, MiFID II, and trade policy' in *The political Influence of Business in the European Union,* (University of Michigan Press, 2019), 80-108, 89; Eckert *Corporate power and regulation*, (Palgrave, 2019).

[99] Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ("the EMA Regulation"), Art. 73.

[100] Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency dated 24 November 2010.

[101] EMA/144064/2019, "Policy on Publication of Clinical Data for Medicinal Products for Human Use", Policy/0070 of 21 March 2019.

[102] Ibid. For a summary of the background surrounding the adoption of this policy see Way et al., op. cit., *supra* note 2.

[103] Ex-Art. 41 of the GFL. The Board adopted a policy under its Decision Concerning Access to Documents of 16 September 2003 available at https://www.efsa.europa.eu/sites/default/files/assets/docsaccess.pdf (accessed 5 April 2021) which entered force on 1 March 2004.

[104] Neither the Pesticides Regulation nor Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (the "Novel Foods Regulation") made such provision.

so in a recital which was therefore not legally binding.[105] Because the EFSA policy also did not align perfectly with the Access Regulation,[106] this created the bizarre and confusing situation where 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.[107]

However, in direct response to the controversy surrounding the reapproval of glyphosate,[108] the EU legislature adopted amendments to the GFL with the aim of improving the transparency of EFSA risk assessments, and which entered into force on 27 March 2021.[109] Replacing the scattershot and varying rights of access under the old regime, the amended Article 41 of the GFL now simply provides that '[the Access Regulation] shall apply to documents held by the Authority,' the legislature specifically recognising the problems for transparency of the interplay between sectoral regulations.[110] 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 reforms do not stop there.

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 …'[111] Thus, in many cases it removes the need for citizens to request certain information, and instead obliges EFSA to proactively disseminate that information. This obligation of proactive publication also applies to a host of other documents held by EFSA including those relating to: proceedings of its Board, Advisory Forum, Scientific Committee and Scientific Panels;[112] its scientific outputs and scientific studies;[113] and a summary of advice provided to potential applicants at pre-submission phase.[114]

Information must be made public 'without delay.'[115] For studies submitted as part of an application for approval, authorisation or renewal this means the non-confidential version of a study in an application for authorisation should be published as soon as the application has been

[105] Recital 21 Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 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") and Recital 20 Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ("Food Additives, Enzymes and Flavourings Regulation").
[106] For example, 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 "undermine" the process.
[107] Art. 18(5) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ("Animal Feed Regulation"), Art. 14(2) Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods ('Smoke Flavourings Regulation' and Art. 18(2) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ("GMO Food and Feed Regulation")
[108] See Arcuri and Hendlin, op. cit. *supra* note 9; and Paskalev, 'On Giving Account and Taking Things into Account: The Case of Glyphosate' TARN Working Paper Series 1/2019 available at: https://privpapers.ssrn.com/sol3/papers.cfm?abstract_id=3316949 (last visited 19 June 2021).
[109] Regulation 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain amended the GFL and It came into force on 27 March 2021.
[110] Regulation 2019/831, ibid, recital 26.
[111] New Art. 38(1)(c) GFL.
[112] New Art. 38(1)(a).
[113] New Art. 38(b) and (d), and (f) respectively.
[114] New Art. 38(i).
[115] Art. 38(1), second indent. See

considered valid or admissible.[116] 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.'[117]

Article 32c provides that EFSA must consult stakeholders and the public in respect of applications for approval, authorisation or renewal of same. 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.[118] 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.[119]

Article 39 still provides certain confidentiality requirements, *inter alia* that applicants for market authorisations may request that certain information be kept confidential including information regarding links between producer and authorisation holder;[120] sourcing, market share or strategy;[121] manufacturing processes[122] and quantitative composition of the substance.[123] However, information in relation to the manufacturing process and quantitative substance composition cannot be kept confidential where it is relevant to assessing safety.[124] Moreover, the applicant must demonstrate that disclosure would 'harm its interests to a significant degree'[125]– a higher threshold than under the Access Regulation. The exception in relation to safety is a potentially powerful tool in the hands of those seeking information around potentially dangerous substances. There are serious concerns around the misrepresentation, misuse, selective use and manipulation of data concerning the safety of substances which have been approved by EFSA.[126] It remains to be seen however how this new exception will be used by those seeking access in years to come and how receptive the EFSA and CJEU will be towards its use.

Finally, before EFSA provides scientific outputs it must now review whether information that has been previously accepted as confidential may nevertheless be made public.[127] This means EFSA is obliged to constantly consider its decisions in relation confidentiality and may, for example, mean that it must reconsider a decision to keep information confidential in light of new scientific knowledge, facts or CJEU case law. The EFSA has also now adopted a number of practical policies and guidelines in relation to transparency.[128] 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.'[129]

---

[116] Art. 39b(1)(a)
[117] Art. 38(1), third indent.
[118] Art. 32c(2)
[119] Ní Chearnaigh, p. 9.
[120] Art. 39(2(b)
[121] 39(2)(c)
[122] Art. 39(2)(a)
[123] Art. 39(2)(d)
[124] Art. 39(2)(a) and (d).
[125] Art. 39(2)
[126] See generally: Robinson et al., op cit *supra* note 86.
[127] Art. 39c.
[128] See: EFSA, 'Transparency Regulation: Practical Arrangements' https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements (last accessed 19 June 2021).
[129] 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) No 1107/2009, Art 3(2).

The GFL reform represents a significant improvement for EFSA transparency and has been referred to as the 'gold standard' in EU transparency rules more generally.[130] As our analysis shows, ECHA is now the clear laggard in terms of transparency of its agency science.

4. Proactive transparency and agency legitimacy

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 as enabling citizen participation and open decision-making. This is reflected in EU Treaty provisions,[131] CJEU jurisprudence, and has been widely discussed in the EU legal academy.[132] 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 CJEU in specific cases and areas.[133] The legislative and interpretative choices analysed in this paper reveal tensions and shortcomings, which are able to undermine the democratic rationale of access to documents in EU risk regulatory procedures with problematic consequences for the legitimacy of and trust in EU agencies and regulation more broadly.

An important conclusion to be drawn from our analysis is that a coherent legal approach to the transparency of EU agency science is missing at the moment. Firstly, 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[134] 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.[135] 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.[136] 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 shall be 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.

Secondly, the Court's case law on general presumptions further fragments the legal right of access, and, moreover, contributes to administrative secrecy. The Court's distinct treatment of

[130] Hofmann and Leino-Sandberg, "An Agenda for Transparency" (European Law Blog, 12 September 2019) <europeanlawblog.eu/2019/10/23/an-agenda-for-transparency-in-the-eu/> (last accessed 31 May 2021). See also 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' (2021) EJRR, first view.
[131] Op.cit. *supra* note 3.
[132] The debate is vast. See e.g. Alemanno, 'Unpacking the principle of openness in EU law: transparency, participation and democracy' 39(1) *European Law Review* (2014), 72-90; Leino-Sandberg, 'Disruptive Democracy: Keeping EU Citizens in a Box' in *The Future of Constitutional Democracy in Europe-A Legal Assessment* (Hart, 2019), 295-316; Mendes, op. cit. *supra* note 5; Koen Lenaerts, 'The Principle of Democracy in the Case Law of the European Court of Justice', 62 *International and Comparative Law Quarterly* (2013), 271-315, 277. Prechal and De Leeuw, op. cit. *supra* note 3; Curtin and Leino, op. cit. *supra* note 15.
[133] They also depend on the actual willingness of the EU institutions to apply these provisions to their fullest extent. See for criticism Leino-Sandberg, *Disruptive Democracy*, op. cit. *supra* note 132.
[134] See Section 1.
[135] 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 EFSA and ECHA have carried out a scientific risk assessment.
[136] See: Art. 41 GFL, Art. 118 REACH, Art. 66 Biocides Regulation and Art. 73 EMA Regulation.

legislative vs administrative transparency[137] has been widely criticized elsewhere[138] and we shall limit ourselves to invoking the core arguments. Such distinction is in tension with the aim of the Access Regulation to 'ensure widest possible access to documents.'[139] The legal justification for such distinction is dubious at best given that the Regulation establishes a single regime of access to documents, as pointed out by several commentators.[140] As Mendes points out, the Court's willingness to grant 'space to think' general presumptions in administrative procedures could be seen as an expression of functional necessities inherent in EU market integration, which require the shielding of certain procedures and which clash with the democratic rationale of the right to access.[141]

The risk regulatory perspective offers additional insights into the problematic nature of general presumptions and administrative secrecy. Any future establishment of such presumptions in risk regulatory procedures, be it for the 'space to think' or for the 'commercial interests' exceptions, could turn out to be altogether counterproductive to the functioning of the risk regulatory procedures in place. The Court's approach seems to follow an outdated understanding of administrative decision-making as being a technical, low-politics exercise, in which openness as a democratic value is of little salience. It is in tension with a rich body of interdisciplinary research studying the politics and epistemic power of scientific expert bodies,[142] as well as the role of transparency in securing expert accountability and agency legitimacy.

The transparency of agency science is considered as crucial for the legitimacy of and public trust in EU risk regulation. Different strands of interdisciplinary scholarship on EU agencies have studied the role of transparency. Studies in political science and public administration offer insights into the ways in which transparency helps improve the democratic accountability, good governance and the legitimacy of EU agencies.[143] From the perspective of science and technology studies and related research on risk regulation and governance, transparency is key to holding scientific advisors to account for the way in which scientific knowledge is being produced and used in public regulation.[144] 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 counter-expertise. From a democratic theory perspective, such practices of public justification and accountability 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.

[137] E.g. *TGI*, *supra* note 27.
[138] Refs, Curtin, op. cit. *supra* note 15; Leino-Sandberg, *Disruptive Democracy*, op. cit. *supra* note 132; Mendes, op. cit. *supra* note 5.
[139] Art. 1 (a).
[140] See: Mendes, op. cit. *supra* note 5; Curtin and Leino, op. cit. *supra* note 15.
[141] On this tension and its historical evolution, see Mendes, op. cit. *supra* note 5.
[142] Deirdre Curtin, 'Challenging Executive Dominance in European Democracy', 77(1) *The Modern Law Review* (2014) 1-32; Weimer and De Ruijter Weimer, Maria, and Anniek de Ruijter (Eds.), *Regulating Risks in the European Union: the Co-production of Expert and Executive power* (Bloomsbury, 2017); Busuioc, *European Agencies: Law and Practices of Accountability* (OUP, 2013).
[143] Bovens, 'Analysing and Assessing Accountability: A Conceptual Framework', 13(4) ELJ (2007), 447-468, 462-463; Madalina Busuioc, 'Accountability, Control and Independence: The Case of European Agencies' 15(5) (2009) ELJ 599; Busuioc, ibid; Schmidt, 'Democracy and Legitimacy in the European Union Revisited: Input, Output and 'Throughput'' 61(1) *Political Studies* (2013) 2-22.
[144] Weimer and De Ruijter, op. cit. *supra* note 142; Korkea-aho, *Adjudicating New Governance: Deliberative Democracy in the European Union* (Routledge, 2015); Busuioc, op. cit. *supra* note 142 and ibid; Holst and Molander, op. cit. *supra* note 5.

citizen exclusion, public alienation, de-politicization) concerns around the use of specialized expertise in public decision-making.[145]

Lastly, we have shown the overall positive contribution of the Aarhus Regulation to strengthening access rights in risk regulation. At the same time, and as the Covid-19 pandemic is raging worldwide, we note the need to create legal provisions which would establish an equivalent presumption of public interest in the disclosure of health-related information. The challenges of science advice for policy demonstrated by the current health crisis are already subject of wide debates[146] and will remain so for the foreseeable future. It is already clear however that transparency plays a key role in building trust in both expert bodies and governments as well as in securing political accountability for Covid19 health measures; and that failures in this regard have undermined public confidence in such measures.[147] A recent inquiry undertaken by the European Ombudsman (EO) into the performance of the European Centre for Disease Prevention and Control (ECDC)[148] during the first year of the pandemic illustrates this point. As part of this inquiry, the EO investigated how the ECDC gathers scientific information, the transparency of such information and broader communication with the public. It found several shortcomings with regard to how the ECDC collected and communicated scientific evidence underpinning its advice. The EO stressed the importance of ensuring the highest standards of transparency taking into account the public's legitimate interest in the quality, completeness and timeliness of the underlying scientific evidence.[149] The EO has called for a more proactive approach to transparency on behalf of the ECDC stating:

> '*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.'*[150]

The findings of this paper suggest that a new proactive approach to transparency of EU agency science across sectors is 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,

---

[145] Holst and Molander, op. cit. *supra* note 5; Christiano, 'Rational deliberation among experts and citizens' in Parkinson and Mansbridge (eds), *Deliberative Systems: Deliberative Democracy at the Large Scale* (CUP, 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).

[146] …

[147] Institute for Government, 'Communications and transparency' https://www.instituteforgovernment.org.uk/publication/whitehall-monitor-2021/transparency (last visited 21 June 2021)

[148] 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, health communication, and the scientific journal *Eurosurveillance*.

[149] European Ombudsman, Decision of 4 February 2021 in strategic inquiry OI/3/2020/TE on how the ECDC gathered and communicated information during the COVID-19 crisis, https://www.ombudsman.europa.eu/en/decision/en/137815 (last accessed 21 June 2021), suggestion 2.

[150] European Ombudsman, Press Release No. 1/2021 published 8 February 2021, 'Ombudsman calls on ECDC to be more open about its work as vaccine rollout begins' https://www.ombudsman.europa.eu/en/press-release/en/137880 (last visited 21 June 2021)

while remaining imperfect, point in this direction.[151] Most importantly, the proactive transparency model of the recently reformed GFL[152] offers an inspiration. It provides a suitably balanced and workable legislative solution that could be applied to other agencies, thereby both harmonising 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'[153] would make it harder for agencies to refuse disclosure while nonetheless ensuring commercial interests are protected where appropriate.

Conclusion

The main finding of this paper is that the current legal approach to the transparency of EU agency science is undergoing significant change as a result of legislative change, agency practice and recent developments of Covid19 pandemic management. The traditional 'passive' approach based on access rights under the EU Access Regulation and applicable sectoral legislation suffers from several shortcomings, is fragmented and outdated requiring urgent reform. We have presented three findings that call for both legislative reform and judicial rethinking. First, our analysis of the CJEU case law 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, and perhaps more broadly. While so far no general presumptions have been established in risk regulation, we highlight recent problematic trends in the case law, which if continued could increase administrative secrecy around EU agency science. Second, we have examined the role of the Aarhus Regulation and its contribution to strengthening rights of access to agency science. 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 further reenforces administrative secrecy. Moreover, at a time of growing awareness of the intertwinement between health and environmental risks, and with the Covid-19 pandemic illustrating the need for transparency of health-related information, new instruments are needed to ensure high standards of transparency not only for environmental, but also for health-related information. Third, our analysis of the EU legal framework for access to documents held by the three EU risk regulation agencies, 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. Most importantly, while EMA and EFSA have moved to a 'proactive' approach based on early publication of all relevant scientific information, ECHA falls below even the standards of the 'passive' approach based on the Access Regulation. We have argued that 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 securing the legitimacy of and trust in EU risk regulation. We welcome the emergence of a new 'proactive' approach to transparency, as embraced among other by the EU General Food Law, as a more promising model to address current and future challenges of risk regulation and crisis management.

[151] See, for example the Commission's publicly accessible Register of Commission Documents https://ec.europa.eu/transparency/documents-register/ (last accessed 21 June 2021) and its Transparency Register https://ec.europa.eu/transparencyregister/public/homePage.do (last accessed 21 June 2021)
[152] See section 1.
[153] GFL, Art. 39(2).