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ARTICLE

Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation

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Abstract

Responding to mistrust in the European agencies' risk assessments in politically salient cases, the European Union (EU) legislator, the European Food Safety Authority and the European Medicines Agency alike have accelerated their efforts to foster EU regulatory science transparency. These simultaneous endeavours have, however, taken place in a fragmented legislative and administrative context, with each agency operating under a different legal framework. By focusing on authorisation procedures, from registration of studies to authorisation of novel foods, pesticides and human medicines, this article examines the resulting regimes governing the disclosure of scientific data by EU agencies to identify common trends and sectoral specificities. Against the background of an overall shift towards enhanced transparency, we shed light on, first, the circulation of institutional arrangements and practices among agencies and, second, the new dimensions of transparency emerging from these developments. We also highlight the remaining sectoral differences and argue that they could have potentially large impacts on the amount and type of information disclosed and on the level of transparency perceived by stakeholders and citizens. We argue that more coherence across the sectoral transparency regimes is needed, in particular in light of the agencies' contested legitimacy and of their increasing cooperation on cross-cutting issues like antimicrobial resistance and medicine and pesticide residues in food.

Keywords: European agencies; human medicines; novel foods; pesticides; risk assessment; transparency

I. Introduction

In the European Union (EU), the collection and assessment of scientific data represents the "core business" of European agencies, and in particular of the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA).[1] In the context of various

[1] See Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety OJL 31, 1 (GFL); Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency OJL 136, 1 (Pharmaceuticals Regulation); the European Chemicals Agency (ECHA) plays a similarly important role in the assessment of scientific studies. As our article focuses on recent developments at the legislative and agency

marketing authorisation procedures, they assess scientific data such as clinical trials and *in vitro* and *in vivo* toxicity studies to assess the quality, safety and efficacy of products. Although most final decisions on market access are taken by the European Commission, it is at the stage of risk assessment that the safety requirements set out in the sectoral legislative frameworks (eg the Pesticides Regulation) are first applied to specific products and individual applicants. In other words, the agencies' risk assessments form the basis upon which the Commission grounds its risk management determinations.[2] Given the Commission's heavy reliance on the agencies' expert opinions,[3] it is crucial that their risk assessment processes live up to a high standard of accountability.

While not being a sufficient condition to ensure accountability, transparency is key in these regards.[4] It makes decision-making processes and the information used therein visible to outsiders and hence contestable.[5] Over the past few years, the transparency of the scientific data underpinning EU risk regulation has been in the spotlight. Public contestation targeted EFSA's allegedly opaque risk assessment process during the reauthorisation of the pesticide glyphosate in 2017.[6] The COVID-19 pandemic brought EMA to the headlines, in particular in the context of vaccines approvals.[7] Calls for more transparency have been accompanied by growing mistrust in regulatory science, often linked to broader concerns over EU agencies' independence vis-à-vis regulated interests and over the very epistemic quality of their assessments.

In both cases of glyphosate and COVID-19 vaccines, public pressure triggered developments in agencies' laws and practices. In the former, it contributed to a broad reform of the General Food Law's (GFL) transparency and risk communication

level, which did not concern ECHA, we do not include chemicals governance in our analysis. See, however, E Hickey and M Weimer, "The Transparency of EU Agency Science: Towards a New Proactive Approach" (2022) 59(3) Common Market Law Review 673; E Korkea-Aho and P Leino, "Who Owns the Information Held by EU Agencies? Weed Killers, Commercially Sensitive Information and Transparent and Participatory Governance" (2017) 54(4) Common Market Law Review 1059.

[2] Eg Art 6(3) GFL.

[3] E Vos and FA Wendler, "Food Safety Regulation at the EU Level" in E Vos and FA Wendler (eds), *Food Safety Regulation In Europe. A Comparative Institutional Analysis* (Cambridge, Intersentia 2006) p 122; D Chalmers, "'Food for Thought': Reconciling European Risks and Traditional Ways of Life" (2003) 66(4) Modern Law Review 532; M Weimer and G Pisani, "Expertise as Justification: The Contested Legitimation of the EU 'Risk Administration'" in M Weimer and A de Ruijter (eds), *Regulating Risks in the European Union: The Co-production of Expert and Executive Power* (London, Hart Publishing 2017) p 167.

[4] A Meijer, "Transparency" in M Bovens, R Goodin and T Schillemans (eds), *The Oxford Handbook of Public Accountability* (Oxford, Oxford University Press 2014) p 507; D Curtin, "'Accountable Independence' of the European Central Bank: Seeing the Logics of Transparency" (2017) 23(1–2) European Law Journal 28, 43; M Bovens, "Analysing and Assessing Accountability: A Conceptual Framework" (2007) 13 European Law Journal 447, 453. See further Section II.

[5] Transparency also entails trade-offs (eg with data protection, the administration's space to think and commercial confidentiality). See infra note 32 and Section II; on commercial confidentiality, in particular, Section III.3.c.

[6] At the core of the dispute were the pesticides' alleged carcinogenicity and concerns over industry manipulation of the studies underpinning EFSA's assessment. See M Morvillo, "From Contestation to Accountability in EU Pesticides Regulation? The Case of Glyphosate" in A Arcuri and F Coman-Kund (eds), *Technocracy and the Law: Accountability, Governance and Expertise* (London, Routledge 2021); C Robinson, CJ Portier, A Cavoski et al, "Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions" (2020) 11(3) European Journal of Risk Regulation 450, 470. See also European Parliament, Parliament resolution of 16 January 2019 on the Union's authorisation procedure for pesticides (2018/2153(INI)), P8_TA(2019)0023.

[7] In relation to the COVID-19 vaccine, calls for more transparency originated from the emergency context characterising its development, the use of novel vaccine platforms, its wide administration and the consistent amount of public funding invested in it. See S Tanveer, A Rowhani Farid, K Hong et al., "Transparency of COVID-19 Vaccine Trials: Decisions without Data" (2022) 27 BMJ Evidence-Based Medicine 199; P Doshi, F Godlee and K Abbasi, "Covid-19 Vaccines and Treatments: We Must Have Raw Data, Now" (2022) 376 BMJ o102.

arrangements[8]; in the latter, it contributed to an unprecedented level of disclosure of clinical studies by EMA.[9] It has been suggested that these developments signal the emergence of a new transparency paradigm in EU risk regulation, characterised by a shift from reactive or passive transparency, based on requests for access to documents, to proactive transparency, whereby agencies take the lead in disclosing the scientific data underpinning their assessments.[10]

While spurred by two crises, these developments seek to address longstanding limitations of the agencies' approach to transparency. First is its high degree of fragmentation.[11] This is partly the result of the nature of the EU's executive, of which European agencies are an integral part. Having developed in the context of the scattered process of "agencification" that characterised the EU in the early 2000s, the establishment of EU agencies has often followed a piecemeal approach.[12] More broadly, lacking a general EU administrative procedure act, EU administrative law itself has – apart from a common core of principles – developed in a sectoralised manner, reflected in the variety of rules governing the different authorisation procedures. In other words, fragmentation characterises both the agencies' founding regulations and the sectoral legislation under which they operate, including rules on transparency. As a result, the same set of scientific studies may be subject to different transparency regimes depending on the applicable authorisation procedure.[13] Given the similarity of the agencies' activities and the EU's constitutional (and horizontal) commitment to transparency, this is difficult to justify on both functional and normative grounds.[14]

Second, scholars have highlighted how agencies across the board exercise broad discretion in deciding whether to disclose scientific studies, in particular vis-à-vis commercial confidentiality claims.[15] The limited legislative guidance upon which they operate resulted in agencies ultimately balancing conflicting interests (confidentiality and disclosure) in what is arguably a stretch of the non-delegation doctrine.[16] In practice, this has been consolidated into an "ownership paradigm", granting the studies' owners substantial control over the type and extent of information disclosed and thereby limiting the actual scope of transparency.[17] The emergence of this paradigm is problematic, as it developed at the margins of the agencies' legislative mandate, crystallising a balance of interests that is not explicitly enshrined in the legislation.

We contribute to these debates by interrogating the recent developments concerning EU agencies' disclosure of scientific studies in light of one main concern: to what extent does the current framework deliver a consistent, cross-sectoral approach to the

[8] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain OJL 231, 1 (GFL reform).

[9] See EFSA transparency policy for COVID-19 vaccines: <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/transparency-exceptional-measures-covid-19-medicines> (last accessed 22 August 2022). On its legal-procedural implications, see A Donati, "The Conditional Marketing Authorisation of Covid-19 Vaccines: A Critical Assessment under EU Law" (2022) 29(1) European Journal of Health Law 33–52.

[10] Hickey and Weimer, supra, note 1.

[11] Korkea-Aho and Leino, supra, note 1; Hickey and Weimer, supra, note 1.

[12] M Chamon, "Transparency and Accountability of EU Decentralised Agencies and Agencification in Light of the Common Approach on EU Decentralised Agencies" in S Garben, I Govaere and P Nemitz (eds), *Critical Reflections on Constitutional Democracy in the European Union* (London, Bloomsbury 2015) pp 245, 251. The 2012 Common Approach on EU decentralised agencies represented a first and "soft" attempt at streamlining the principles governing EU agencies, including – albeit to a limited extent – transparency.

[13] Hickey and Weimer, supra, note 1, 695–96.

[14] ibid, 709.

[15] Korkea-Aho and Leino, supra, note 1, 1064.

[16] ibid, 1064.

[17] ibid, 1090.

transparency of agency science, in particular with regard to the balancing between disclosure and the protection of commercially confidential information (CCI)? With this question in mind, we carry out a comprehensive comparative analysis of the law and practices governing each stage of the approval and authorisation procedures of novel foods and pesticides (EFSA)[18] and pharmaceuticals for human use in the centralised authorisation procedure (EMA).[19]

The two policy areas on which we focus (pharmaceuticals and food governance) are representative of scientific studies' peculiar collocation at the interface of science and regulation. They contain complex information that needs to be interpreted and evaluated by experts. At the same time, they form the basis of agencies' determinations, which in turn substantively impact the Commission's decisions. What is more, the vast majority of the scientific studies relied upon by EU risk regulatory agencies is generated and submitted by businesses applying for product authorisations. Conducting such studies is a resource-intensive activity, and control over the data contained therein represents a substantive advantage in markets, such as that of pesticides or pharmaceuticals, which are highly competitive.[20] Within these two areas, we investigate the state of agency science's transparency, starting from three authorisation procedures: novel foods, pesticides and human medicines. These procedures share a science-intensive nature, a common set of legislative aims[21] and high societal and political salience, as the debates surrounding glyphosate, COVID-19 vaccines and the role of alternative proteins[22] prove. They have also all been affected by recent legislative and agency efforts to foster regulatory science's transparency. Notwithstanding these common features and trajectories, the respective transparency regimes continue to present subtle but relevant differences, on which we shed light.

As we set out to delve into our analysis, we need to address a fundamental question: besides EU agencies, what is the broader normative case for transparency in risk regulation? After all, one could argue, it is a complex and highly technical field, where transparency is unlikely to be conductive to accountability. We address this question in Section II, where we examine the normative goods served by transparency in risk regulation and show how they are reflected in the EU's horizontal approach to transparency. We then consider the sectoral frameworks governing the disclosure of scientific data in the three selected areas, focusing on both the pre-marketing and marketing phases (Section III). Here, we complement the legal analysis with a focus on the agencies' own implementation of both horizontal and sectoral legislation to understand how agency transparency works in practice.[23] Section IV discusses the findings and identifies new dimensions of

[18] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel food, OJL 327, 1 (NFR); Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market, OJL 309, 1 (Pesticides Regulation).

[19] Pharmaceuticals Regulation (n 1). Other procedures exist (eg the mutual recognition and decentralised procedure, the introduction of variation to an existing marketing authorisation or the authorisation of manufacturing), which will not be dealt with here.

[20] As proven by the high number of requests for access to documents brought by competitors (Korkea-Aho and Leino, supra, note 1, 1062); see also EMA, "Annual Report 2021" <www.ema.europa.eu/en/documents/annual-report/2021-annual-report-european-medicines-agency_en.pdf> p 136 (last accessed 22 August 2022).

[21] Ie protection of human health and the environment, the functioning of the internal market and the promotion of industrial and agriculture policy. See Art 1(3) Pesticides Regulation; Art 1(1) GFL; Art 1(2) NFR; Recital 13 Pharmaceuticals Regulation.

[22] European Commission, "FOOD 2030 Pathways for Action. Alternative proteins and dietary shift" (2020) <https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/2020.2057_en_05.pdf> (last accessed 22 August 2022).

[23] The analysis in Section III is primarily based on EFSA's and EMA's internal policies and guidance implementing horizontal and sectoral transparency legislation. All of the agency documents consulted are publicly available through the respective institutional websites.

transparency, common trends and sustained fragmentation in EU agencies' disclosure of scientific data. In Section V, we conclude that, whilst the legislative frameworks governing the transparency of scientific information are informed by similar principles and follow comparable trends, important and arguably problematic differences remain in how transparency is delivered in practice.

II. The role of transparency in risk regulation

Transparency is a multifaceted concept.[24] It is a value in itself, as well as one that serves multiple other normative goods, ultimately enhancing the legitimacy of decision-making.[25] In general, transparency fosters democratic decision-making and participation. By making decision-making processes and the information on which they rely visible, this allows citizens to engage with, shape, evaluate and contest them and their outcomes, adding to the input dimension of legitimacy.[26] Transparency also promotes public trust and accountability. It enables public control over the exercise of public authority, allowing the detection of abuses and fostering citizens' confidence in the public interest orientation of legislative and regulatory outcomes.[27] It is also a precondition for accountability: the visibility of decision-making processes and of the underlying information is essential for accountability fora to be able to hold actors to account.[28] Transparency also entails trade-offs with other legally protected goods, such as commercial confidentiality, data protection and the administration's space to think.[29] Its actual meaning and scope are therefore the outcomes of constant balancing and re-negotiation.

To what extent do these rationales hold true in a field such as risk regulation, which is characterised by a high level of technical complexity? According to the Court of Justice of the European Union (CJEU), complexity does not interfere with transparency's

[24] In the EU context, Alemanno critically notes that the term has often been used interchangeably with "openness" to indicate the opposite of opaqueness and secrecy (A Alemanno, "Unpacking the Principle of Openness in EU Law: Transparency, Participation and Democracy" (2014) 39(1) European Law Review 72). In this broad sense, it entails citizens' access to documents and proactive publication. See Hickey and Weimer, supra, note 1, and infra, this section.

[25] D Curtin, *Executive Power of the European Union* (Oxford, Oxford University Press 2011) p 204 et seqq; V Schmidt, "Democracy and Legitimacy in the European Union Revisited: Input, Output and 'Throughput'" (2013) 61(1) Political Studies 2; for the concept of "normative goods", see M Dawson and A Maricut, "Procedural vs Substantive Accountability in EMU Governance: Between Payoffs and Trade-Offs" (2021) 28(11) Journal of European Public Policy 1707; see also V Abazi and E Tauschinsky, "Reasons of Control and Trust: Grounding the Public Need for Transparency in the European Union" (2015) 11(2) Utrecht Law Review 78. However, see also C Hood and D Heald, *Transparency: The Key to Better Governance?* (Oxford, Oxford University Press 2006).

[26] Schmidt, supra, note 25.

[27] M Morvillo, "Why Should Citizens Trust EU Regulatory Expertise? Legal Warrants, Science and Politics in EU Food Governance" in R Barradas de Freitas and S Lo Iacono (eds), *Trust Matters. Cross-Disciplinary Essays* (London, Hart Publishing 2021) p 229.

[28] The relationship between transparency and accountability is, however, not free from ambiguities. See C Hood, "Accountability and Transparency: Siamese Twins, Matching Parts, Awkward Couple?" (2010) 33(5) West European Politics 989. See supra, note 24.

[29] Commercial confidentiality is particularly relevant in science- and innovation-intensive domains, such as those analysed in this article. We focus on this in Section III.3.c. On transparency and the agencies' "space to think" and privacy and data protection, see L Leone, "EFSA under Revision: Transparency and Sustainability in the Food Chain" (2020) 39 Yearbook of European Law 536–68; D Way, *Transparency in Risk Regulation: The Case of the European Medicines Agency* (PhD thesis, King's College London 2017); S Chatzopoulou, NL Eriksson and D Eriksson, "Improving Risk Assessment in the European Food Safety Authority: Lessons From the European Medicines Agency" (2020) 11 Frontiers in Plant Science 349; AC Egilman, A Kapczynski, ME McCarthy et al, "Transparency of Regulatory Data across the European Medicines Agency, Health Canada, and US Food and Drug Administration" (2021) 49 Journal of Law, Medicine & Ethics 456; Korkea-Aho and Leino, supra, note 1.

legitimacy-enhancing potential. In particular, it enhances institutions' effectiveness and accountability and, "by allowing divergences between various points of view to be openly debated, it also contributes to increasing those citizens' confidence in those institutions".[30] While the Court seems oblivious to the knowledge asymmetries between experts and laymen, these represent a serious obstacle to the realisation of transparency's legitimacy-enhancing potential.[31] In risk regulation, effective transparency assumes the further nuance of comprehensibility.[32] What counts is not only the amount of information disclosed, but also its quality, and especially its intelligibility by a non-expert audience. In this sense, in risk regulation even more than in other fields, transparency mechanisms need to be carefully designed so as to avoid making transparency obligations a purely performative exercise.[33]

The specificity of risk regulation as a highly technical and politically contentious field results in two additional normative goods that transparency can deliver. The first is epistemic legitimacy: transparency enables a broader peer-review process, reaching beyond regulatory expertise towards the scientific community. As a result, cognitive errors and biases are less likely to go unnoticed, improving the overall epistemic soundness of the science underpinning risk regulatory measures. The second binomial of context-specific goods is open science and innovation. Open science pursues the wider accessibility of scientific publications, the underlying methodologies, including protocols and research plans,[34] and (when possible) raw and/or cleaned data.[35] In doing so, it makes the scientific process more inclusive and democratic, contributes to avoiding the duplication of studies – in particular trials – and fosters innovation.[36]

The way in which transparency relates to these normative goods in a given legal system depends on the legal framework governing it. In the EU, transparency's role is well established at the constitutional level. As of today, it is enshrined in Article 11 TEU and Articles 15(1) and (3) TFEU, which introduced the right of access "to documents of the Union's institutions, bodies, offices and agencies, whatever their medium". It is, however, through secondary legislation that transparency is harnessed into actionable mechanisms. The main EU horizontal frameworks are those set out by the Access Regulation[37] and the Aarhus Regulation.[38] Here, transparency is balanced with other interests such as commercial confidentiality, data protection and privacy and the protection of institutions' "room

[30] Case T-716/14 *Tweedale v EFSA* [2019] ECLI:EU:T:2019:141, para 54; Case C-57/16 P, *ClientEarth v Commission* [2018] ECLI:EU:C:2018:660, para 75.

[31] See F Vibert, *The Rise of the Unelected: Democracy and the New Separation of Powers* (Cambridge, Cambridge University Press 2017).

[32] W Wagner, *Incomprehensible! A Study of How Our Legal System Encourages Incomprehensibility, Why It Matters, and What We Can Do About It* (Cambridge, Cambridge University Press 2019).

[33] On the pitfalls of transparency in technically complex contexts, see, eg, M Scholten, M Maggetti and Y Papadopoulos, "Towards a Comprehensive System of Controls for EU Agencies" in M Scholten and A Brenninkmeijer (eds), *Controlling EU Agencies* (Cheltenham, Edward Elgar Publishing 2020) pp 315–18; T Schillemans and M Busuioc, "Predicting Public Sector Accountability: From Agency Drift to Forum Drift" (2015) 25(1) Journal of Public Administration Research and Theory 191. See also E Fisher, "Exploring the Legal Architecture of Transparency" in P Ala'i and RG Vaughn (eds), *Research Handbook on Transparency* (Cheltenham, Edward Elgar Publishing 2014).

[34] J-C Burgelman, C Pascu, K Szkuta et al, "Open Science, Open Data, and Open Scholarship: European Policies to Make Science Fit for the Twenty-First Century" (2019) 2 Frontiers in Big Data 43.

[35] National Academies of Sciences, Engineering, and Medicine, *Open Science by Design: Realizing a Vision for 21st Century Research* (Washington, DC, National Academies Press 2018).

[36] OECD, "Making Open Science a Reality" (2015) *OECD Science, Technology and Industry Policy Papers*, No. 25.

[37] 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, OJL 145, 43 (Access Regulation).

[38] 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 OJ L264/13 (Aarhus Regulation).

to think". The Access Regulation establishes the principle of the "widest possible access"[39] for all to the documents generated and held by the Parliament, Council and Commission. It also applies to EFSA and EMA via the respective founding Regulations[40] and, importantly, to third-party documents held by the agencies, such as the scientific data submitted by the applicants in the context of product authorisations. The Access Regulation's preamble expresses a clear commitment to the democratic-participatory and the accountability rationale:

> (2) Openness enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system. Openness contributes to strengthening the principles of democracy and respect for fundamental rights ...

The Regulation also establishes exceptions, notably including the protection of commercial interests, privacy and ongoing decision-making processes, which should be overridden by proven public interest in disclosure.[41]

The second horizontal transparency framework is the Aarhus Regulation.[42] Sharing the Access Regulation's rationales, it operates as *lex specialis* and only applies to environmental information.[43] It sets out the transparency obligations of EU institutions and bodies, expressly including agencies, and, similar to the Access Regulation, it pursues the objective of the "widest possible" dissemination of information.[44] In so doing, it establishes that whenever environmental information is at stake, an overriding public interest in disclosure is presumed. The reach of the exceptions set out in Article 4(2) of the Access Regulation is therefore limited and their interpretation narrowly framed.[45] As a result, under EU law, environmental information benefits from an enhanced transparency standard.

When considering secondary legislation, it is important to keep in mind that the ways in which transparency contributes to the legitimacy of EU regulatory science are greatly dependent on the interaction between the horizontal frameworks considered above, sectoral legislation and agency-specific practices. In particular, while some of the balancing choices between transparency and confidentiality are made at a primary and, mostly, secondary level, others are "outsourced" to sectoral legislation, as well as guidance and other soft law measures (see Table 1).

III. The sectoralised approach to transparency in novel foods, pesticides and human medicinal products

Sectoral legislation governs the lifecycle of medicines, pesticides and novel foods[46] from the laboratory to the market.[47] We follow its various phases and discuss the rules and

[39] Art 1(1) Access Regulation.

[40] Art 73 Pharmaceuticals Regulation; Art 41 GFL.

[41] Art 4 Access Regulation. See further Section III.3.c.

[42] 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, OJ L 264, 25.9.2006, 13 (Aarhus Regulation).

[43] Art 2(1)(d) Aarhus Regulation. See M Morvillo, "The General Court Orders Disclosure of Glyphosate-Related Scientific Studies: *Tweedale*, *Hautala*, and the Concept of Environmental Information in the Context of Plant Protection Products" (2019) 10(2) European Journal of Risk Regulation 419.

[44] Art 1(1) Aarhus Regulation.

[45] Art 6(1) Aarhus Regulation.

[46] Novel foods and pesticides both rely on the GFL and can often be discussed jointly.

[47] With the exclusion of post-marketing stages.

Table 1. Overview of legislation, agencies' internal policies and guidance governing transparency in agency science for human medicines and food.

	Human medicines	Food	
	Access Regulation (1049/2001)		
Horizontal legislation	–	Aarhus Regulation (1367/2006)	
Vertical legislation: (1) agency level	*EMA* Regulation 2309/1993 Regulation 726/2004	*EFSA* Regulation 178/2002 (GFL) Regulation 1381/2019 (GFL reform)	
Vertical legislation: (2) sector-specific	*Human medicines clinical trials* Regulation 563/2014	*Pesticides* Regulation 1007/2009	*Novel foods* Regulation 2283/2015
Process-specific aspects: (1) notification of studies	Directive 2001/20/EC	GFL and GFL reform	
Process-specific aspects: (2) pre-submission advice	EMA guidance on pre-submission advice	EFSA decision on pre-submission advice EFSA transparency decision	
		Pesticides EFSA confidentiality decision on pesticides	*Novel foods* –
Process-specific aspects: (3) authorisation: access to documents, proactive publication and commercially confidential information	Policy 0043 (2018) Policy 0070 (2016)	EFSA decision on access to documents EFSA Standard Operating Procedure for public access to documents EFSA decision on transparency and confidentiality	

Horizontal legislation lays the foundation of transparency in agency science, subsequently complemented by vertical legislation at the agency and sector level. These feed into the transparency requirements laid down in agency policy and guidance documents addressing specific components of the procedure.
EFSA = European Food Safety Authority; EMA = European Medicines Agency; GFL = General Food Law.

policies governing the transparency of scientific data therein. Starting with the pre-submission phase, we consider, first, the notification and disclosure of studies, which will later be used by applicants to support their marketing authorisation application, and, second, the pre-submission advice provided by the agency and its transparency. We then examine the approval/authorization process, distinguishing between proactive publication by agencies and publication as a reaction to access documents requests. In both cases, the understanding of what constitutes CCI is crucial to determining the actual scope of transparency.

1. Notification of studies

The collection of the scientific data included in the application dossier starts months – often years – before its submission.[48] Increasingly often, potential applicants must notify

[48] Data requirements for marketing authorisations are set out in sectoral legislation. See Implementing Regulation EU No 2017/2469 for novel foods; Regulations 283 and 284/2013 for active substances and plant protection products; Annex 1 Directive 2001/83 for human medicines: here, the documentation required depends on the type of authorisation (eg originator products, generics, biosimilars). D Hullova, CD Simms, P Trott and P Laczko,

the competent agency of the studies they intend to carry out to support their application. Notification obligations respond to several concerns: first, ensuring the completeness of the scientific data on which the agency bases its assessment, and in particular avoiding applicants withholding unfavourable studies; second, in the case of human medicines, the protection of trial participants; and third, study registration on online registries[49] fosters open science and, by improving the reproducibility of studies, minimises the risk of bias, strengthening research credibility.[50]

In the EU, all three sectors considered require studies to be notified. While for medicines notification of studies is an established practice, in the food sector it is one of the innovations introduced by the 2019 reform of the GFL. Yet, notification regimes differ in both rationale and scope. For human medicines, the notification of studies is aimed at protecting study participants; in the food sector, it is aimed at safeguarding the scientific quality and independence of EFSA's assessments by ensuring the completeness of the application dossier and avoiding the withdrawal of unfavourable studies. In terms of scope, in food-related procedures *all* of the studies linked to an application must be notified. The "new" Article 32b GFL provides for a notification system according to which both businesses and laboratories are obliged to notify EFSA of any study commissioned to support an application, on which the Agency has to provide a scientific opinion.[51] A similarly comprehensive requirement is absent in the EU's medicines framework. Here, the notification obligation only concerns clinical trials. It is, however, more far-reaching, as potential applicants do not simply need to register their studies, but rather they need to apply for an authorisation with the Member State where the trial is to be carried out due to any potential risks and ethical concerns.[52]

In both cases, the accessibility of the registered studies remains limited. EFSA collects the notifications in a database, which is only accessible to applicants and laboratories[53] until the application or notification is received by EFSA,[54] and which is subsequently subject to the general transparency regime set out in Articles 38 and 39e GFL. Upon conclusion of the procedure, EMA publishes in a database the information on the authorised trials, including data on the manufacture and control of the product and data from non-clinical (eg toxicology) studies and from its clinical use. Personal data and CCI are also excluded here.[55]

2. *Pre-submission advice*

When compiling their application dossier, potential applicants can seek the competent agency's advice. Pre-submission advice serves multiple purposes: from the regulators'

"Critical Capabilities for Effective Management of Complementarity between Product and Process Innovation: Cases from the Food and Drink Industry" (2019) 48(1) Research Policy 339, 345.

[49] Pre-registration of various types of studies is increasingly supported (eg the Open Registries Network: <osf.io/registries>). See also B Bert, C Heinl, J Chmielewska et al, "Refining Animal Research: The Animal Study Registry" (2019) 17(10) PLoS Biology e3000463.

[50] See M Munafò, BA Nosek, DVM Bishop et al, "A Manifesto for Reproducible Science" (2017) 1 Nature Human Behaviour 0021; B Nosek, "The Pre-Registration Revolution" (2017) 115(11) Proceedings of the National Academy of Science of the United States of America 2600–06; National Academies of Sciences, Engineering, and Medicine, supra, note 35.

[51] The notification should be made without delay when starting the study and contain its title and scope, the name of the parties involved and the starting and planned completion date. Failure to notify the studies or to include their results in the dossier without a valid justification results in the application's inadmissibility.

[52] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJL 121, 34–44.

[53] With the exception of renewals, see infra.

[54] Art 32(b)(7) GFL.

[55] See Arts 81(4) and (5) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, OJ L 158, 1 (Clinical Trials Regulation).

perspective, it fosters compliance by ensuring that applicants have a clear understanding of the regulatory requirements. From the applicant's perspective, it increases the chances of presenting an admissible application and diminishes the risk of carrying out studies that will later be deemed invalid for substantiating the quality, safety or efficacy of their products.

As with study notification, pre-submission advice has been an integral part of EMA's procedures since its inception,[56] but it is a relative novelty for food governance, having been introduced with the 2019 GFL reform.[57] Interestingly, while the scope of EFSA's advice is now clearly defined in legislation, EMA developed its own internal guidance starting from a rather vague legislative basis. In both cases, advice is non-binding (for the agencies) and non-committal (for the applicant)[58]: it therefore does not entail any consequences for the actual scientific assessment that the agencies will carry out once the application is submitted.[59] The features of pre-submission advice differ significantly across and within agencies. It can be voluntary (EFSA, except for renewals; EMA) or mandatory (EFSA renewals)[60] and may be subject to the payment of a fee (EMA).[61] In terms of scope, it can include study design (EMA; EFSA renewals)[62] or be limited to specific elements of the application (eg content and applicable rules; EFSA).[63]

If pre-submission advice is to be (and to appear externally) in line with the agencies' impartiality when assessing the application, it should be provided as openly as possible. As of 2019, following a European Ombudsman decision,[64] EMA includes in its public assessment report (EPAR) – published only once the procedure is concluded – a summary of the questions and advice discussed in the pre-submission stage.[65] The GFL reform drew partly on EMA's lesson, requiring EFSA to publish a summary of the pre-submission advice.[66]

[56] See Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products OJL 214, 1. Art 51(j), now Art 57(n) Pharmaceuticals Regulation.

[57] Arts 32(a)(1) and 32(c)(1) GFL.

[58] EMA's website stresses that advice does not equate a pre-decision on the quality, safety or efficacy of the product: <https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance> (last accessed 22 August 2022). For EFSA, see Art 32(a)(1) GFL and Art 11, Decision of the Executive Director of the European Food Safety Authority Laying down practical arrangements concerning confidentiality in accordance with Arts 7(3) and 16 of Regulation (EC) No 1107/2009 (EFSA confidentiality decision on pesticides).

[59] To this end, the agency officials providing pre-submission advice are separate from those assessing the dossier. EMA provides pre-submission advice via the Scientific Advice Working Party (SAWP), established within the Committee for Human Medicinal Products (CHMP). For EFSA, see Art 32(a)(1) GFL.

[60] See Art 57(1)(n) Pharmaceuticals Regulation and EMA, European Medicines Agency Guidance for Applicants seeking scientific advice and protocol assistance, EMA/4260/2001 Rev. 13, 31 March 2022 (EMA guidance on pre-submission advice). In the food sector, for first authorisations, see Art 32(a)(1) GFL; for renewal of an existing authorisation, see Art 32(c)(1) GFL. See also Arts 9 and 10 EFSA Decision laying down the practical arrangements on pre-submission phase and public consultations, 23 December 2020 (EFSA decision on pre-submission advice).

[61] Such a fee is waived for the development of innovative medicines for unmet medical needs (PRIME Scheme, Orphan medicinal products).

[62] See EMA guidance on pre-submission advice, 5; Art 32(c)(1) GFL.

[63] Art 32(a)(1) GFL. For pesticides, see also Art 6(2) EFSA confidentiality decision on pesticides.

[64] See European Ombudsman, "Decision in strategic inquiry OI/7/2017/KR on how the European Medicines Agency engages with medicine developers in the period leading up to applications for authorisations to market new medicines in the EU", 17 July 2019; more recently, see also European Ombudsman, "Letter to the European Medicines Agency (EMA) concerning the transparency and independence of the work of the EMA in supporting the development and evaluation of COVID-19 medicines", Case SI/5/2020/DDJ, 20 July 2020. The Ombudsman recommended the publication of information regarding the pre-submission advice, including the experts involved, after the authorisation of the medicine.

[65] EMA guidance on pre-submission advice, 22.

[66] Art 38(1)(i) GFL; Art 14(5) EFSA decision on pre-submission advice.

Summaries are published once the application is declared admissible or valid,[67] and, importantly, without the possibility to request confidential treatment.[68]

3. Marketing authorisation and approval procedures

a. Reactive publication: access to documents

Until recently, reactive publication (ie publication following individual access to documents requests under the Access Regulation and the Aarhus Regulation) has been the main channel of agency science's visibility.[69]

EMA's first access to documents policy dates back to 2006[70] and was subsequently reformed in 2010 (Policy 0043)[71] and 2018.[72] According to Policy 0043, EMA ensures the widest possible access to documents concerning "any matter related to the policies, activities and decisions falling within [its] remit and responsibilities".[73] For such requests, the exceptions laid out in Article 4 of the Access Regulation apply, after having consulted the third party involved[74] and unless there is an overriding public interest in disclosure.[75] Where EMA finds that confidentiality concerns only parts of the documents, it redacts them and makes available the remainder of the document. Until 2019, the EMA's approach led the way, especially as compared to EFSA's 2003 document on openness, transparency and confidentiality.[76] The GFL reform has, however, resulted in a significant advancement of EFSA's access to documents policy by including an explicit reference to the Access and Aarhus regulations in the GFL.[77] As a result, EFSA's Management Board decision on access to documents mandates a strict interpretation of the exceptions to access to documents.[78] When considering exceptions based on the protection of CCI or of the agencies' internal deliberations, EFSA must ascertain the existence of any overriding public interest in disclosure "notwithstanding the fact that the interests in question would thereby be undermined".[79] The Decision also acknowledges the CJEU's judgments in *Tweedale* and *Hautala*, ratifying the higher transparency standard for information concerning emissions into the environment.[80]

[67] Art 38(7) GFL; Art 5(2)(f) Decision of the Executive Director of the Authority laying down the practical arrangements concerning transparency and confidentiality, 19 January 2021 (EFSA transparency decision).

[68] Art 5(2)(f) EFSA transparency decision.

[69] The agencies share the commitment to "ensuring wide access": Art 80 Pharmaceuticals Regulation; Art 41(1) GFL.

[70] See EMA, Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents, 19 December.2006, EMEA/MB/203359/2006 Rev 1 Adopted.

[71] EMA, European Medicines Agency policy on access to documents, Policy 0043, 30 November 2010, EMA/110196/2006 (Policy 0043 (2010)).

[72] EMA, European Medicines Agency policy on access to documents, Policy 0043, 4 October 2018, EMA/729522/2016 (Policy 0043 (2018)).

[73] ibid, 2.

[74] ibid, 4.1.2.

[75] ibid, 4.1.2. and Annex. The policy also makes clear that, in order to protect EMA's internal deliberation, documents will only be released once the procedure has been finalised.

[76] EFSA, "Openness, transparency and confidentiality" MB 16 September 2003 – 13 – Agreed (EFSA Openness Policy) para 5.

[77] Art 41 GFL as amended by the GFL reform. See also EFSA Decision of the Management Board laying down practical arrangements for implementing Regulation (EC) No 1049/2001 and Arts 6 and 7 of Regulation (EC) No 1367/2006, wp200327-a2, 27 March 2020 (EFSA decision on access to documents); EFSA Standard Operating Procedure. Applications for Public Access to Documents (PAD), SOP_036_A, 25 January 2021.

[78] Art 8.1 EFSA decision on access to documents.

[79] Art 8(3) EFSA decision on access to documents.

[80] Art 9(2) EFSA decision on access to documents.

b. Proactive publication: raising the standard of transparency

Alongside reactive publication, agencies are now increasingly required to proactively (ie without being solicited) publish scientific data. The scope and modes of such publication are, however, differentiated, in particular since the GFL reform, which has made proactive publication one of the flagship strategies to increase the transparency of EFSA's risk assessments but has not yet been complemented by an EMA equivalent.

EMA has an established proactive publication policy, with the EPAR as its main dissemination channel. After the conclusion of the procedure, it publishes details about the authorised product and the authorisation procedure, including the reasons underpinning the EMA committee's opinion and excluding CCI.[81] In addition, EMA has been the first pharmaceutical regulator worldwide to proactively disclose clinical trials data, as described in Policy 0070.[82] While the policy was discontinued in 2018, due to the Agency's increased workload following its relocation to Amsterdam and later the COVID-19 pandemic, the Clinical Trials Regulation now enshrines proactive publication of clinical trials at a legislative level.[83] Based on the Regulation, EMA publishes all information concerning clinical trials conducted in the EU, including summary information – regardless of the marketing authorisation status but excluding CCI.[84]

Compared to EMA, EFSA had been lagging behind until the GFL reform.[85] The "new" Article 38(1) GFL significantly widened the scope of proactive publication obligations, and EFSA now needs to publish the "scientific data, studies, and other information supporting applications, including supplementary information supplied by applicants" (lett. c), "the information on which its scientific outputs, including scientific opinions, are based" (lett. d) and "a summary of the advice provided to potential applicants at pre-submission phase" (lett. i). To foster proactive publication of all documentation submitted to EFSA whilst allowing the agency sufficient time to assess confidentiality requests, the GFL now requires applicants to provide both non-confidential and confidential versions of the dossier, with the former being published once the application is deemed valid.[86] These innovations are mirrored in sectoral legislation[87] and have been translated into practical arrangements,[88] which highlight the importance of proactive

[81] Arts 13 and 57(b) Pharmaceuticals Regulation; EMA, Reflection paper: EPAR summary for the public, 26 January 2006 EMEA/126757/2005. The EPAR is published even in case of negative opinion or application withdrawal (Art 11 Pharmaceuticals Regulation; EMA, Procedural advice on publication of information on negative opinions and refusals of marketing authorisation applications for human medicinal products, 2 May 2013, EMA/599941/2012; EMA, Procedural advice on publication of information on withdrawals of applications related to the marketing authorisation of human medicinal products, 25 June 2013, EMA/599977/2012 rev. 1).

[82] EMA, European Medicines Agency policy on publication of clinical data for medicinal products for human use, POLICY/0070, 2 October 2014 (EMA/240810/2013) (EMA Policy 0070). The "usual" limits (post-authorisation publication, protection of personal data and CCI) applied. D Kim, "Transparency Policies of the European Medicines Agency: Has the Paradigm Shifted?" (2017) 25(3) Medical Law Review 456–83; S Bonini, H-G Eichler, N Wathion and G Rasi, "Transparency and the European Medicines Agency – Sharing of Clinical Trial Data" (2014) 371(26) New England Journal of Medicine 2452–55.

[83] Clinical Trials Regulation.

[84] Art 81 Clinical Trials Regulation. See EMA, "Clinical trials in the European Union" (2022) <https://euclinicaltrials.eu/home> (last accessed 22 August 2022).

[85] Art 38 GFL required EFSA to disclose a range of internal documents including "the information on which its opinions are based" without prejudice to the provisions governing confidentiality and access to documents.

[86] Art 39(a)(2) GFL as amended by the GFL reform; Art 4(4)(a) EFSA transparency decision.

[87] See Art 23(1) NFR; Arts 10 (new active substances) and 16 (renewals) Pesticides Regulation.

[88] EFSA transparency decision.

disclosure,[89] detail the types of information that can and cannot be considered for confidential treatment[90] and prescribe the timeline for its publication.[91]

While EMA's focus on clinical trials is justified due to their importance for authorisation (in terms of safety, efficacy and ethics), EFSA's approach to proactive transparency is significantly more comprehensive, applying to all studies and raw data included in the dossier.

c. The protection of commercially confidential information

In all of the stages considered so far, the meaning and extent of both reactive and proactive publication are highly dependent on the interpretation of the exceptions to disclosure. CCI, in particular, is one of the legally protected interests to be balanced with the public interest in disclosure and can result in redaction of documents (both in the case of reactive and proactive publication) and denial of access (especially in relation to reactive publication).

The concept of CCI has undergone a gradual clarification at the sectoral level, insofar as neither the Access Regulation nor the Aarhus Regulation provides a definition when listing it as one of the exceptions to access to documents. EMA guidance documents first characterised CCI as falling broadly into two categories:

- confidential intellectual property, "know-how" and trade secrets (including e.g. formulas, programs, process or information contained or embodied in a product, unpublished aspects of trade marks, patents etc.);
- commercial confidences (e.g. structures and development plans of a company).[92]

The EMA revised its policy in 2018.[93] As of today, CCI includes information that is not yet in the public domain or otherwise publicly available and whose disclosure may undermine the owner's economic interest or competitive position. Clinical data are generally excluded from CCI.[94] Detailed agency guidance implementing the Clinical Trials Regulation provides further insights into what constitutes CCI in this context: legitimate economic interests, in particular, relate to whether sponsors of a clinical trial intend to seek a marketing authorisation for the product that is being investigated or to whether information from a trial may contribute to obtaining future research funds.[95] Relevant factors are therefore the nature of the trial and the product being studied, but not, for example, the status of the sponsor.

The CJEU and the European Ombudsman have also played a significant role in defining the meaning of CCI in the pharmaceutical context. The case of the anti-inflammatory drug Humira is emblematic. Upon request of the producer, the General Court had granted interim measures stopping EMA from releasing three clinical study reports due to the need

[89] ibid, recitals 4–7.

[90] Arts 5 and 6 EFSA transparency decision. Information in relation to which requests for confidential treatment can be submitted include: (lett. c) non-confidential versions of the scientific data, studies and other supporting information submitted by applicants, published without delay once a valid and admissible application has been received; and (lett. i) the information upon which EFSA bases its output, published without delay after adopting the relevant scientific output. Confidentiality requests are not admitted in relation to, eg, summaries of pre-submission advice.

[91] Art 11 EFSA transparency decision.

[92] EMEA, Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents, 15 April 2007, EMEA/45422/2006.

[93] EMA Policy 0070, paras 3 and 4.

[94] ibid, paras 3 and 4; see also Annex 3.

[95] EMA, Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited – EMA/42176/2014", 2 October 2015 EMA/228383/2015 Endorsed.

to protect CCI.[96] Upon appeal, the Court of Justice overturned the General Court's order, stressing that the likelihood of "serious and irreparable damage" had not been sufficiently established.[97] In the meantime, however, EMA and the applicant had made out-of-court agreements concerning the redaction of the documents. The Ombudsman initiated an own-initiative inquiry on the issue, concluding that all redactions must be duly justified and calling upon EMA for more proactive transparency.[98] In 2018, cases in front of the General Court further clarified the scope of CCI, highlighting that not all information concerning a company or its business relationships is immediately considered commercially sensitive, insofar as Article 4(2) of the Access Regulation requires the applicant to provide detailed justification.[99] These decisions confirmed the trend inaugurated by Policy 0070 and Policy 0043: all information is in the public domain unless the applicants provides compelling arguments to the contrary.

In the food sector, EFSA has long operated under limited (legislative or administrative) guidance. Its first attempt at defining the scope of commercial confidentiality dates back to its 2003 document on openness, transparency and confidentiality. Instead of putting forward a set of criteria to identify CCI, EFSA followed a case-by-case approach (ie discussing directly with the interested companies how to interpret CCI).[100] This changed with the 2019 GFL reform. Article 39(2) GFL now specifies that confidential treatment can be requested only for information related to: the manufacturing or production process; commercial links between producers/importers and applicants; commercial information revealing sourcing, market shares or business strategies of applicants; or the quantitative composition of the substance for which authorisation/application is requested – as long as such information is not relevant for safety assessments. These innovations are reflected – and further detailed – in sectoral legislation on novel foods[101] and pesticides.[102] In all of these cases, applicants must prove that disclosure would harm their interests "to a significant degree".[103] Internal agency guidance further elaborates on this qualified burden of proof, with EFSA's transparency decision requiring applicants to explain in plain language the reasons justifying confidential treatment. These must fulfil six cumulative requirements: (1) the document is not publicly available; (2) its disclosure may harm the interests of the applicant to a significant degree; (3) the potential harm is quantifiable at least to 5% of the gross annual turnover/earnings for the previous year;[104] (4) it is eligible for legal protection/has not been unlawfully acquired; (5) it does not fall under the definition of "environmental information" (Article 2 of the Aarhus Regulation); and (6) it has been finalised up to five years prior to the submission of the confidentiality request.[105]

[96] Order in Case T-44/13 R *AbbVie v EMA* [2013] ECLI:EU:T:2013:221.

[97] Case C-389/13 P(R) *EMA v AbbVie* [2013] ECLI:EU:C:2013:794.

[98] European Ombudsman, Decision in case OI/3/2014/FOR, 8 June 2016.

[99] Case T-718/15 *PTC Therapeutics International Ltd v EMA* [2018] ECLI:EU:T:2018:66 and Case T-235/15 *Pari Pharma GmbH v EMA* [2018] ECLI:EU:T:2018:65; S Röttger-Wirtz, "The EMA Access to Documents Policy Put to Trial" (2018) 2(2) European Pharmaceutical Law Review 108.

[100] EFSA Openness Policy, para 6; Korkea-Aho and Leino, supra, note 1, 1072–73.

[101] Arts 23(4)(a) and (b) NFR include information concerning starting substances or preparations and their use, detailed information on the nature and composition of the food in which the substance will be used and detailed analytical information on variability and stability of individual production batches.

[102] Arts 39(2)(b), (c) and (d) Pesticides Regulation include specifications related to impurities of the active substances and related measurements, as long as these impurities are not (eco-)toxicologically or environmentally relevant; results of production batches; and information providing details about the complete composition of a plant protection product; see also EFSA Confidentiality decision on pesticides.

[103] Art 39b GFL; Art 23(4) NFR; Art 63(2) Pesticides Regulation.

[104] Neither reasons underlying this number nor the elements to be included in the calculation of the damage (eg reputational damage) are clear.

[105] Art 10 EFSA transparency decision; further procedural requirements are laid out in Art 9(4)(b) EFSA transparency decision.

Taken together, the GFL reform and EFSA's guidance set a rather high bar for the protection of CCI.

In the case of pesticides, these developments have been accompanied – and encouraged – by the CJEU's case law. Even before its landmark judgments in *Tweedale* and *Hautala*,[106] the Court had been supportive of calls for more transparency. In particular, it emphasised that exceptions to the principle of the widest possible access, including the scope of CCI, should be construed strictly,[107] and it interpreted broadly the concept of environmental information and the link between toxicity studies on pesticides and emissions into the environment.[108]

In a nutshell, while EMA still enjoys considerable discretion when assessing the meaning and scope of CCI based on its internal guidance, the food sector has shifted from a case-by-case approach to a much more comprehensive legislative framework, which significantly constraints the Agency's discretion when developing and applying its own guidance. This difference could originate from the fact that, for human medicines, only clinical trials are published proactively, whereas for other documents reactive transparency remains the default. For the former, the scope of CCI is clearly defined, while for the latter a case-by-case approach is deemed sufficient. EFSA, on the other hand, being required to publish more documents proactively, needs a detailed and "centralised" approach to the definition of CCI. This explanation does not seem entirely convincing, as proactive and reactive disclosure appear increasingly as two sides of the same coin, to the effect that applying different standards for one or the other could lead to paradoxical results. What the two agencies share is placing the burden of proof as to the need for confidential treatment on the applicant, requiring it to prove that, first, there is a commercial interest at play and, second, that such an interest would suffer significant damage from disclosure.

IV. Persisting fragmentation in an evolving legal landscape

The path towards increased transparency of EU agency science has been shaped by scandals and legal and political contestation. EMA represents a good example in these regards. Upon its establishment, the Agency was heavily criticised for its opaqueness.[109] As a combined result of internal policies, CJEU and European Ombudsman decisions[110] and legislative reform,[111] it evolved into a pioneer of proactive transparency in terms of both the amount and type of information disclosed. EFSA has also recently undergone a comprehensive legislative reform, responding to both the glyphosate crisis[112] and the CJEU's decisions,[113] further advancing the frontier of proactive transparency.[114] These developments feed into a broader trend from a system based on the *incidental* disclosure achieved through the right to access to documents to more *systemic* transparency.[115] While the former has played an important role in shaping the transparency of agency science as

[106] *Tweedale*, supra, note 30; Case T-329/17 *Heidi Hautala and Others v European Food Safety Authority* [2019] ECLI:EU:T:2019:142.

[107] Case C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe* [2016] ECLI:EU:C:2016:889, para 53.

[108] ibid; Case C-442/14 *Bayer CropScience and Stichting De Bijenstichting* [2016] ECLI:EU:C:2016:890.

[109] R Löfstedt, "Transparency at the EMA: More Evidence Is Needed" (2013) 47(3) Therapeutic Innovation & Regulatory Science 299.

[110] European Ombudsman, "Decision of the European Ombudsman Closing his Inquiry into Complaint 2560/2007/BEH against the European Medicines Agency" (24 November 2010).

[111] Clinical Trials Regulation.

[112] GFL reform.

[113] See *Tweedale*, supra, note 30 and *Hautala*, supra, note 106.

[114] Hickey and Weimer, supra, note 1.

[115] ibid. For a comprehensive picture of the evolution of transparency and openness in the EU legal system, see Alemanno, supra, note 24.

we know it today, notably through the involvement of judicial (the CJEU) and quasi-judicial (the European Ombudsman) actors, proactive transparency entails a change of perspective, whereby scientific data inherently belong to the public domain unless otherwise substantiated by clear and compelling interests in confidentiality. The shift from reactive to proactive transparency could have significant repercussions for the importance of access to documents as a tool to ensure transparency. Will it become a "residual" instrument, to be used in cases such as pre-submission advice where disclosure is limited to summary versions of the actual documents? The question remains open, and it should be addressed in the long-awaited reform of the Access Regulation.[116]

In terms of chronological development, the shift from reactive to proactive transparency has been taking place through a circulation of mechanisms between the agencies. EMA, in particular, has inaugurated several of the tools, which have now been adopted in the food sector through the GFL reform: registration of studies, pre-submission advice and, more generally, proactive disclosure of scientific data. Building on EMA's experience, the GFL reform has brought openness to a new level. Scientific studies benefit from a presumption of publicness (see the submission of a double dossier and the consideration *ex ante* – ie regardless of requests for access to documents – of any claim of confidentiality), which reaches much further than EMA's clinical data policy, encompassing all of the scientific data submitted by the applicants. One can wonder whether the higher transparency level set by the amended GFL represents a further step in the incremental development of transparency in EU agencies, which will "circle back" to EMA and trigger similar developments with regards to medicines authorisations.

As of today, however, the analysis confirms the fragmented approach to transparency in EU agencies, whereby horizontal legislation acquires different nuances depending on the sectoral legislation (and agencies' policies) complementing it. Such variations concern both procedure (eg see notification of studies and pre-submission advice) and substance (eg the extent of information disclosed and the definition of CCI). Several factors could contribute to explaining this persistent fragmentation. Among these, first is the fact that the overhaul of the transparency framework in food governance is a reaction to two context-specific developments: the glyphosate crisis and the (connected) *Tweedale* and *Hautala* judgments, whose reach, as of today, is limited to environmental information; and second, the different features of the regulated sectors, with the pharmaceutical industry having been found to rely more on technological innovations protected by trade secrets as opposed to its agri-food counterpart.[117]

While these factors might all play a role in and, at least to some extent, support the fragmented framework of EU agency science transparency, their justificatory potential appears weak in areas such as antimicrobial resistance and medicine and pesticide residues in food, in which agencies are increasingly required to cooperate.[118]

[116] The reform of the Access Regulation (COM(2008) 229 final; COM(2011) 137 final) has been stalled for a decade after the adoption of the European Parliament's position.

[117] S Ciliberti, L Carraresi and S Bröring et al, "Drivers of Innovation in Italy: Food versus Pharmaceutical Industry" (2016) 118(6) British Food Journal 1292–316 analysed drivers of innovation in the food industry versus the pharmaceutical industry in Italy. In line with existing literature, the authors describe that the food industry works with more incremental innovations, "characterised by a low degree of newness".

[118] See ECDC, EFSA and EMA "Third Joint Inter-Agency Report on Integrated Analysis of Consumption of Antimicrobial Agents and Occurrence of Antimicrobial Resistance in Bacteria from Humans and Food-Producing Animals in the EU/EEA" (2021) 19(6) EFSA Journal 6712, 164; EMA, "Draft report on development of a harmonized approach to 4 exposure assessment methodologies for residues from 5 veterinary medicinal products, feed additives and 6 pesticides residues in food of animal origin", 30 June 2022, EMA/CVMP/499555/2021.

One of the dimensions of the highlighted fragmentation, which appears particularly problematic from an EU constitutional law perspective, is the variation in the level of discretion entrusted to EFSA and EMA by the respective sectoral legislation. While the GFL reform goes quite deep into the details of the type of information that might be granted confidential treatment and of the invokable grounds against its disclosure (eg the 5% harm quantification threshold), the legislative framework for medicines leaves a much broader space for EMA to define relevant elements of its approach to transparency, which is mostly detailed in internal policies, building on rather open-ended legislative provisions. Extensive reliance on internal guidance rather than legislation is problematic from the point of view of democratic legitimacy and legal certainty, insofar as it leaves a delicate balancing of interests in the hands of the Agency, thus making such matters more likely to be decided on a case-by-case basis. While a degree of discretion is inevitable, the GFL seems to provide clearer guidance to EFSA than Regulation 726/2004 does to EMA.

Finally, our analysis signals several developments in the nature of the normative goods pursued through transparency. Besides the pursuit of democracy and accountability already enshrined in horizontal transparency legislation, the needs to ensure public trust, epistemic quality and open science have started to feature more prominently in both legislation and agencies' policies on proactive publication. EMA Policy 0070 mentions enabling public scrutiny as one of its goals.[119] Public confidence features prominently in the GFL reform, whose preamble reads:

> (12) Transparency of the risk assessment process contributes to greater legitimacy of the Authority being acquired in the eyes of the consumers and general public in the pursuit of its mission, increases their confidence in its work and ensures that the Authority is more accountable to the Union citizens in a democratic system. It is therefore essential to strengthen the confidence of the general public and other interested parties in the risk analysis underpinning the relevant Union law, and in particular in the risk assessment, including the transparency thereof as well as the organisation, functioning and independence of the Authority.

References to transparency as promoting epistemic quality are present in relation to EFSA's pre-submission advice on the studies proposed in the context of authorisation renewals, insofar as the public consultation envisaged therein aims at taking into account existing experience and knowledge on the product.[120] EMA also refers to proactive publication as a tool allowing researchers to reassess clinical data.[121] The role of the scientific community as a peer reviewer is therefore acknowledged by both agencies.

Finally, open science increasingly features as one of transparency's benefits. The application of the new knowledge developed through clinical trials to future research is mentioned among the objectives of EMA Policy 0070.[122] Similarly, striving for making data available and accessible has resulted in the development of a dedicated portal (OpenEFSA) in which information related to EFSA's work and activities can be found.[123]

[119] EMA Policy 0070, para 4.1.

[120] Recital 12 GFL reform.

[121] See EMA, "Clinical Data Publication" (2022) <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication> (last accessed 22 August 2022).

[122] ibid. See also EMA Policy 0070, para 4.1.

[123] See EFSA, Questions and answers one EFSA practical arrangements, 32–33 and EFSA Strategy 2027, Science, Safe Food, Sustainability, mb210624-a2, 24 June 2021, 13. S Cappè, M Gilsenan, E O'Dea et al, "Editorial: The Future of Data in EFSA" (2019) 17(1) EFSA Journal 3.

What remains to be seen is whether and to what extent proactive transparency, as implemented by the agencies, will ensure the comprehensibility of the disclosed information, without which transparency's democracy- and accountability-enhancing effects would be difficult to attain. The Pharmaceuticals Regulation explicitly established that the EPAR should include "a summary written in a manner that is understandable to the public".[124] The GFL reform similarly reflects a concern for the actual accessibility of the disclosed information by developing a comprehensive approach to risk communication.[125] The next years will prove whether the shift towards proactive transparency has resulted in increased agency legitimacy and innovation.

V. Conclusion

"Never waste a good crisis" – this expression seems to fit the developments that led to increased transparency of scientific data in food and pharmaceutical authorisation and application processes. As a result of legislative reform, litigation and European Ombudsman decisions, the transparency of EU agency science is now approached more proactively and confidentiality has come to be interpreted in an increasingly strict manner across the board. Overall, amendments to sectoral legislation have brought the various approaches to the transparency of scientific studies closer together. Still, the devil is in the details: across the life cycle of authorisation and approval procedures for novel foods, pesticides and human medicines, differences remain as to the type of information made available, the extent to which such information is published proactively rather than as a reaction to access-to-documents requests and the timing of its publication. The identified differences affect the overall reach of transparency and its perception amongst stakeholders and citizens.

Our analysis of the life cycle of product authorisations contributes to the debates on the transparency of EU agency science through three main findings. First, we shed light on the circulation of transparency mechanisms between the two agencies considered. Many of the novelties characterising EFSA's new approach to transparency find their roots in the law and practices governing the transparency of medicinal products and have been exported and adapted to the food sector through the GFL reform. As a result, EMA, once a pioneer of transparency, is now to some extent lagging behind EFSA.

Second, within this "circular" dynamic regarding proactive transparency, we identify specific regulatory junctures where sectoral differences remain. We discuss the factors and sectoral specificities that could contribute to explaining such variations. In particular, the two sectors seem to differ in terms of innovation dynamics and of the role so far played by environmental concerns. Still, we argue that these regulatory differences remain problematic considering the increasing trend towards an integrated approach to health and environmental concerns in risk regulation, whereby agencies are required to cooperate on cross-cutting issues such as antimicrobial resistance and medicine and pesticide residues in food. In these cases, further coherence would be needed, in particular with regards to weighing the public interest in disclosure with protection of CCI. Ultimately, a more consistent cross-sectoral framework would enhance the legitimacy of the output provided by the agencies from both an epistemic and a democratic perspective.

Third, we show that the move towards proactive transparency has broader implications: on the one hand, it might result in a back-staging of the right to access to documents in the context of agency science, reducing the Access Regulation to a residual mechanism

[124] Art 13(3) Pharmaceuticals Regulation.
[125] Arts 1(1) and (2) GFL reform. See Morvillo, supra, note 27, 229.

to be activated when proactive publication fails to deliver effective transparency. On the other hand, proactive publication fosters new dimensions of transparency, such as epistemic quality and open science. Complementing the traditional participation- and trust-enhancing functions of transparency, these implications could contribute to strengthening the overall legitimacy of expert-based measures in EU risk regulation.

Competing interests. The authors declare none.

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