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DOI:
[10.1017/cel.2015.3](https://doi.org/10.1017/cel.2015.3)

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Document Version
Peer reviewed version

Citation for published version (Harvard):
Vaughan, S 2015, 'Differentiation and Dysfunction: An Exploration of Post-Legislative Guidance Practices in 14 EU Agencies', *Cambridge Yearbook of European Legal Studies*, vol. 17, no. 1, pp. 66-91.
<https://doi.org/10.1017/cel.2015.3>

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Checked November 2015

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DIFFERENTIATION AND DISFUNCTION: AN EXPLORATION OF POST-LEGISLATIVE GUIDANCE PRACTICES IN 14 EU AGENCIES

STEVEN VAUGHAN[#]

ABSTRACT:

This paper offers up a map of self-authored post-legislative guidance practice among the EU's decentralized agencies. It shows that the use of guidance by EU agencies is widespread and significant, but not pervasive in that 14 of the EU's 33 agencies currently engage in guidance making. Where guidance is produced, it varies significantly between and within agencies as regards volume and length. These documents are hard to find, they are called a miscellany of different things and there seems to have sprang up, ad hoc, a hierarchy to guidance that is both interesting and lacking in clarity. The question as to whether such guidance binds those to whom it has been addressed has been fudged, with agencies and courts engaging in exercises of tautology and misdirection to avoid the appearance of anything that looks like binding norm making by the EU's agencies. Consultation and participation in the making of guidance seems lackadaisical. This map suggests a level of differentiation that is so ill thought out, and so ad hoc, so lacking in foresight and oversight, as to be dysfunctional. At the same time, the lack of engagement by the EU courts with these norms suggests that the site of opportunity for a way forward in this area lies other than with the judiciary.

KEYWORDS

European Union, Agencies, New Governance, Guidance, Hybridity, Soft Law, Rulemaking

Since 1975 agencies have been a part of the EU institutional landscape,¹ although more than half of the current suite of EU agencies were created in the last decade,² following enlargement, the intensification of the internal market and the widening of EU competences.³ The EU's appetite for such agencies is said to be 'limitless',⁴ and Madalina Busuioc has argued that EU, 'agencification has arisen, grown and progressed in the shadow of the law, without an explicit basis in the treaties.'⁵ Geographically located across the EU, these 33 decentralized agencies have legal personality, pool expertise and carry out a variety of

[#] University of Birmingham. I am very grateful to Aleksandra Cavoski, Elizabeth Fisher, Maria Lee, Robert Lee, Joanne Scott, the editors and the anonymous reviewer for comments on an earlier draft. The usual disclaimer applies.

¹ When CEDEFOP and EUROFOUND were both established.

² M Busuioc, *European Agencies: Law and Practices of Accountability* (OUP, 2013) p14

³ V Hatzopoulos, 'Hard to Soft: Governance in the EU Internal Market', (2012) *Cambridge Yearbook of European Legal Studies* 101, p127

⁴ D Geradin and N Petit, 'The Development of Agencies at EU and National Levels: Conceptual Analysis and Proposals for Reform' (Jean Monnet Working Paper 01/04, 2004) p4

⁵ Busuioc, note 2 above at p5

technical, managerial and scientific tasks.⁶ But they do not, supposedly, also promulgate regulation or engage in policy making. Unlike independent regulatory agencies in the US,⁷ there is a ‘theoretical bar’ on EU institutions delegating to EU agencies powers that have been conferred on those institutions by the Treaties.⁸ However, it has been argued that some EU agencies have so much power, and so much autonomy, that they ‘stretch the boundaries of the legal [non-delegation] doctrine to the maximum.’⁹ The focus of this paper lies in what powers, if any, have been granted via legislation to each of the EU’s 33 agencies to produce self-authored guidance. On a much more practical level, this paper also explores how those powers have played out in the real world: the volume of guidance those agencies have produced; what it looks like; where it is kept; how the agencies speak of it; how easy the guidance is to find etc.¹⁰

Governance in the EU can be understood as a complex world of hybrid rules in which legislative and non-legislative texts and tools issued from a variety of sources interact with each other in multiple ways from ‘not at all’ to wholly fused on multiple levels, amid of a constellation of public and private actors.¹¹ This paper is concerned with post-legislative guidance, norms that are yoked onto underpinning hard law,¹² as one aspect of that complex world, and offers up a map of post-legislative guidance practice among the EU’s decentralised agencies.¹³ This map, of a ‘plural legal landscape’,¹⁴ allows for five conclusions to be drawn. First, self-authored post-legislative guidance by EU agencies is widespread, but not pervasive. Second, ‘guidance’ takes a multiplicity of forms, reinforcing some of the core ideas of new governance approaches as flexible, diverse and experimental.¹⁵ In this paper,

⁶ http://europa.eu/about-eu/agencies/index_en.htm

⁷ XA Yataganas, ‘Delegation of Regulatory Authority in the European Union: The Relevance of the American Model of Independent Agencies’ (Jean Monnet Working Paper 03/01, 2001)

⁸ C Harlow and R Rawlings, *Process and Procedure in EU Administration* (Hart Publishing, 2014) p244. This non-delegation doctrine originated in 1958 in the case of *Meroni v High Authority*, C-9/56, EU:C:1958:133. For a discussion of *Meroni*, and its impacts, see: Busuioc, note 6 above at p18 ff. In a more recent case on *Meroni*, the European Court of Justice held that because the powers of an EU agency were “precisely delineated and amenable to judicial review in the light of the objectives established by the delegating authority” those powers were *Meroni* compliant. See: *UK v European Parliament and Council*, C-270/12, ECLI:EU:C:2014:18, para 53

⁹ Busuioc, note 2 above at p19. See also: S Griller and A Orator, ‘Everything under Control? The Way Forward for Agencies in the Footsteps of the Meroni Doctrine’ (2010) 35 *European Law Review* 3; and E Chiti, ‘European Agencies’ Rulemaking: Powers, Procedures and Assessment’ (2013) 19(1) *European Law Journal* 93

¹⁰ Between February and April 2015, I reviewed the websites of the EU’s decentralised agencies. I took a threefold approach to finding the guidance documents. First, I searched the website for the terms ‘guidance’ and ‘guidelines’. Second, I explored the website sections variously headed ‘Publications’, ‘Document Libraries’, ‘Documents’ etc. Third, I had a much less methodical play with the website: looking to see how it was structured and organized, how topics/issues were grouped together etc. I accept this is not, perhaps, the most robust of all methodologies, but the aim in this paper is to provide an introduction and overview to, rather than the final word on, these issues.

¹¹ For a wider review of the possible connections and disconnections between different aspects of EU governance, see: KA Armstrong, ‘The Character of EU Law and Governance: From ‘Community Method’ to New Modes of Governance’ (2011) 63 *Current Legal Problems* 179. For a more general review of EU policy making, see: H Wallace, MA Pollack and AR Young (eds), *Policy-making in the European Union*, 6th ed (Oxford University Press, 2010)

¹² The concept of ‘yoking’ comes from Trubek and Trubek. See: DM Trubek and LG Trubek, ‘New Governance and Legal Regulation: Complementarity, Rivalry and Transformation’, (Wisconsin Law School Legal Studies Research Paper Series No 1047, May 2007)

¹³ For the full list of these agencies, see Appendix 1 to this paper. For reasons of brevity, I have used the agencies’ acronyms rather than their full names.

¹⁴ KA Armstrong, ‘Differentiated Economic Governance and the Reshaping of Dominium-Law’ (University of Cambridge Legal Studies Research Paper Series, 7/2014) p2

¹⁵ G de Búrca and J Scott (eds) *Law and New Governance in the EU and the US* (Hart Publishing, 2006); G de Búrca, C Kilpatrick and J Scott (eds) *Critical Legal Perspective on Global Governance: Liber Amicorum David M Trubek* (Hart Publishing, 2014)

‘guidance’ is used as a shorthand overarching term to encompass those post-legislative instruments that are called ‘guidance’ and those which are called something else - guidelines, guides, formats, common approaches, position papers, advices, nutshells, handbooks, technical guides, standards, FAQs etc¹⁶ - but which fulfill the same function.¹⁷ My focus, for this paper, is specifically and solely on guidance which is self-authored by the EU agencies and bears their names. I am not interested in guidance issued by others (e.g. the Commission) which EU agencies use or adopt. As such, I am concerned with an agency’s own sense of its functions and how it will carry them out; and not with constraints placed on an agency by guidance authored by those delegating authority to that agency. This focus arises because the capacity of an agency to expand its competences through guidance might not be compliant with the theoretical bar (discussed above) on non-delegation of regulatory powers to EU agencies.

The third conclusion that can be drawn from this paper is that the nature of guidance is, on the face of it, poorly understood by those who issue it, particularly in the context of its bindingness. Fourth, it is very unclear as to who is permitted to input into what guidance and when. This raises importance issues of participation. Fifth, and relatedly, public access to these guidance documents operates as a function of the (often poor) quality of the respective agency websites.

The remainder of this paper unfolds in four parts. Part one situates this paper within the field of scholarship on new governance and hybrid law. Part two is the map of post-legislative guidance practice. Part three looks at how post-legislative guidance has been understood by the EU courts. To précis, the cases on post-legislative norms (compared to other, non-yoked forms of soft law) are few in number and say very little of substance. The final part of this paper argues that what we see with post-legislative guidance practice among the EU’s decentralised agencies is not only differentiated but dysfunctional, and requires intervention.

I. NEW GOVERNANCE AND HYBRID LAW

Much of the early work in the new governance field is on contrasts: on setting out and exploring the dichotomies between old and new governance, and between hard and soft law. What this paper will show is that post-legislative practice in the EU is more complex, more nuanced and messier than can be accounted for via some of the simple dyads to which some new governance scholars have previously been drawn.¹⁸ New governance scholarship has been criticised for its ‘definition-by contrast’ approach and for idealising the ‘new’ over the ‘old’.¹⁹ This is in spite of the origins of this body of scholarship in offering up a critical

¹⁶ Each of these terms is used by one or more of the EU agencies under review in this paper. Such diversity has also been seen with post-legislative guidance issued by the Commission – see: H Hofmann, ‘Negotiated and Non-Negotiated Administrative Rule-Making - The Example of EC Competition Policy’ [2006] 43 *Common Market Law Review* 153

¹⁷ In other work, I have argued that the functions of post-legislative guidance can be fourfold: (i) such can amplify or expand on the underlying hard law; (ii) that guidance can standardize the actions of those subject to the law; (iii) it can translate the law (i.e. where guidance implicitly contests and goes against the drafting of the underlying law, ‘translating’ the relevant provisions into something else); and/or (iv) post-legislative guidance can extrapolate from the law (i.e. guidance can fill in the gaps where the legislative text is silent on a given matter). See: S Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar, 2015)

¹⁸ In *Bund für Umwelt*, AG Jaaskinen notes that the different parties to case had used the same Commission policy document to argue opposite points: *Bund für Umwelt v Germany*, C-461/13, EU:C:2010:773, point 106

¹⁹ On the former, see: G de Búrca and J Scott, ‘Introduction’ in G de Búrca and J Scott (eds), *Law and New Governance in the EU and US* (Hart Publishing, 2006). On the latter, see: KA Armstrong, ‘New Governance

review of the, ‘normative qualities of different “old” and “new” forms of governance in the EU, and their compatibility with the principles of the rule of law and democracy.’²⁰ Binary distinctions do not account for variations in policy development or in the implementation, assessment and/or justiciability of various instruments.²¹ While dichotomies provide clear bright lines, and as such are attractive, there is a risk that these binary understandings ‘undersell and under-explain’ changes that are occurring in the functions and definitions of law and governance.²²

It is important to move the debate beyond what I see as the rather blunt typologies of soft norms that have compared ‘preparatory and informative instruments’ with ‘interpretative and decisional instruments’;²³ and ‘soft regulatory rule-making’ (involving para-law policy-steering instruments) with ‘soft administrative rule-making’ (involving post-legislative guidance instruments).²⁴ I am trying very hard in this article to avoid a regurgitation of the differences between hard and soft law because I am not convinced that such: (a) is helpful; and/or (b) explains adequately what we see with the hybrid world of post-legislative guidance.²⁵ What this paper shows is that the hard law/soft law distinction is no longer fit for purpose as it no longer accurately reflects new governance in the EU. I would also agree with Kenneth Armstrong that the time has perhaps come to abandon the concept of ‘soft law’ as such is, ‘both over- and under-inclusive in its capacity to capture changes in law and governance.’²⁶ These arguments tend towards the conclusion that that we may need to seriously reconsider, and reframe, the boundaries of law to account for the breadth and depth of post-legislative guidance practice.²⁷

As a phenomenon and as a field of scholarship, new governance is a broad church.²⁸ As an approach, new governance seeks to explore, understand and critique changes in EU governance as they move away from traditional, top-down, command and control modes of regulation (associated with the Community Method) and towards deliberative, diverse, flexible, decentralized, experimental, multi-level, reflexive and participatory forms of decision-making.²⁹ Gráinne de Búrca has suggested that the rise of new governance systems

and the European Union: An Empirical and Conceptual Critique in G de Búrca, C Kilpatrick and J Scott (eds) *Critical Legal Perspective on Global Governance: Liber Amicorum David M Trubek* (Hart Publishing, 2014)

²⁰ C Joerges and M Weimer, ‘A Crisis of Executive Managerialism in the EU: No Alternative?’ in G de Búrca, C Kilpatrick and J Scott (eds), *Critical Legal Perspective on Global Governance: Liber Amicorum David M Trubek* (Hart Publishing, 2014)

²¹ C de la Porte and P Pochet, ‘Why and how (still) study the Open Method of Co-ordination (OMC)?’ (2012) 22 *Journal of European Social Policy* 336, p339

²² KA Armstrong and C Kilpatrick, ‘Law, governance, or new governance - the changing open method of coordination’ (2007) 13(3) *Columbia Journal of European Law* 649, p654

²³ L Senden, *Soft Law in European Community Law* (Hart Publishing, 2004) p118

²⁴ L Senden and T van den Brink, ‘Checks and Balances of Soft EU Rule Making’ (Report for the European Parliament, March 2012), p12; L Senden, ‘Soft Post-legislative Rulemaking: A Time for More Stringent Control’ (2013) 19(1) *European Law Journal* 57, p60. Edoardo Chiti takes a similarly blunt approach in his work in this area: see note 9 above

²⁵ For those wanting a more rigorous review of soft law, see: F Snyder, ‘The Effectiveness of EC Law’ (1993) 56(1) *MLR* 19; Senden, notes 23 and 24 above; and Senden and van den Brink, note 24 above

²⁶ Armstrong, note 19 above at p262 ff. See also: Armstrong and Kilpatrick, note 22 above

²⁷ Armstrong, note 19 above at p249

²⁸ On the former, see DM Trubek and LG Trubek, ‘The Coexistence of New Governance and Legal Regulation: Complementarity or Rivalry?’ (Paper, Annual Meeting of the Research Committee on the Sociology of Law, Paris, July 2005); G de Búrca and J Scott, ‘New Governance, Law and Constitutionalism’ in G de Búrca and J Scott (eds), *Law and New Governance in the EU and the US* (Hart Publishing, 2006); and G de Búrca, ‘New Governance and Experimentalism: An Introduction’ (2010) 2 *Wisconsin Law Review* 227. On the latter, see: Armstrong, note 19 above

²⁹ J Scott and DM Trubek, ‘Mind the Gap: Law and New Approaches to Governance in the EU’ (2002) 8 *European Law Journal* 1, p16; Armstrong and Kilpatrick, note 22 above at p654

can be seen as a response to two background conditions: the first is ‘the need to address complex policy problems which have not shown themselves readily amenable to resolution’; and the second is the need to manage interdependence where divergent national regulatory regimes affect one another.³⁰

The formal frameworks of EU law, the Treaties, do not reflect modern EU governance. As Linda Senden puts it, ‘the catalogue of sources and hierarchy of norms in Articles 288 to 291 of the TFEU are of misleading simplicity’ and belie the many other instruments that have emerged in the EU’s institutional practice over time.³¹ There is no reference to soft norms or hybrid law in the categories of EU Treaty norms. Despite this, there has been a notable increase in the use of legislative guidance in the EU. This, Joanne Scott observes in the context of EU environmental law, is a product of increasing legislative complexity and a marked reliance on broad and imprecisely defined framework norms.³² There are good reasons for the use of legislative guidance. The time the legislature has to consider legislation is limited, and some matters will necessarily be left for further debate. Equally, legislative knowledge at the point of law making can be incomplete and imperfect,³³ requiring elaboration in the post-legislative phase. In this way, post-legislative guidance has the potential to act as a corrective mechanism to flaws, gaps and/or missed opportunities. Equally, there will always be discretion in how legislative norms are interpreted, expanded on and operationalized.

The term ‘hybrid’ is used in multiple ways in the context of EU law. It might be deployed to describe situations where regulation is multi-modal (for example, an instrument which combines both informational regulation plus some self-regulation),³⁴ and/or where a given matter is controlled by both public and private forms of ordering.³⁵ For new governance scholars, early notions of hybridity, including those by David Trubek and Louise Trubek and by Grainne de Búrca and Joanne Scott, refer to all situations in which hard and soft law complement each other, existing in the same field to promote the same goals (and as such could be co-legislative, extra-legislative or post-legislative).³⁶ My interest is solely in the post-legislative, the situation in which post-legislative, non-legislative norms are fused, or yoked, onto underlying legislation. Here, self-authored guidance issued by EU agencies is a classic example of hybrid law. Trubek and Trubek argue that when new governance approaches are ‘yoked together in a hybrid form’ with conventional forms of regulation, we see a ‘real *transformation* in the law.’³⁷ These hybrids are said to represent a new form of law

³⁰ de Búrca, note 28 above at p232

³¹ Senden, note 24 above, p57

³² J Scott, ‘In Legal Limbo: Post-Legislative Guidance as a Challenge for European Administrative Law’ (2011) 48 *Common Market Law Review* 329, p330

³³ M Wilkinson, Three Conceptions of Law: Towards a Jurisprudence of Democratic Experimentalism, (2010) *Wisconsin Law Review* 673, p682. Maria Lee has suggested that, in the context of the Water Framework Directive (WFD), post-legislative activity might have been a necessary part of the WFD’s ambitious approach. See: M Lee, ‘Law and Governance of Water Protection Policy’ in J Scott (ed) *Environmental Protection: European Law and Governance* (OUP 2009)

³⁴ D Levi-Faur, ‘Regulation and Regulatory Governance’ (JPRG Paper No. 1, February 2010)

³⁵ Carolyn Abbot and Maria Lee argue that, ‘The inclusion of private actors in EU environmental governance, and indeed in other areas of regulation at all levels, is absolutely routine.’ See: C Abbot and M Lee, ‘Economic actors in EU environmental law’ (2015) 34(1) *Yearbook of European Law*

³⁶ Trubek and Trubek, note 28 above; de Búrca and Scott, note 28 above

³⁷ Trubek and Trubek, note 12 above, p3. See also: DM Trubek, P Cottrell and M Nance, ‘Soft Law, Hard Law and European Integration: Toward a Theory of Hybridity’ (University of Wisconsin Legal Studies Research Paper No. 1002, 2005)

and, as such, are ‘of special interest’.³⁸ I would agree, and yet the scholarship on hybrid law in this context is quite limited, although growing.³⁹

There are those who set out valid concerns in the use of post-legislative guidance: concerns about legitimacy, accountability and justiciability.⁴⁰ These may well equally apply to other forms of delegated/implementing acts.⁴¹ In a recent paper on EU sovereign debt instruments, Claire Kilpatrick sets out four potential problematic ‘Rule of Law challenge’ dimensions to the legislation she reviews.⁴² Three of these are also relevant to this paper: (i) complexity; (ii) inaccessibility (the relevant norms are hard to find); and (iii) incomprehensibility (as only English speakers can comprehend the majority of the sources).⁴³ These dimensions are discussed below.

II. POST-LEGISLATIVE GUIDANCE AMONG 14 EU AGENCIES

In this part of the paper, I map the differentiated self-authored post-legislative guidance practices among the EU’s decentralised agencies. What we see is that while the use of such guidance by these agencies is widespread, it is not pervasive. We also see that such guidance varies significantly in its length, in its formats, and in the grant of power via EU legislation to the agencies to produce the guidance. There is significant variation in the extent to which different publics, different stakeholders, are able to input into guidance making, and as regards ease of access to those documents. We further see, with some agencies, what appears to be a hierarchy of guidance, which raises interesting questions about the pluralisation of norms as part of the EU project.

A. The Use of Guidance

Of the 33 EU agencies reviewed for this paper, 14 produced post-legislative guidance and 15 did not.⁴⁴ Of the four agencies that remain, the SRB,⁴⁵ a new EU agency established in January 2015 to step in when a bank in the EU fails or is about to fail, has the power to issue guidance,⁴⁶ but has not yet done so. EU-LISA has not published any guidance documents, but its 2013 Activity Report suggests that ‘subject specific guidance’ will be issued in the

³⁸ Trubek and Trubek, note 12 above, p5

³⁹ E Korkea-aho, ‘Legal Interpretation of EU Framework Directives: A soft law approach’ (2015) 40(1) *European Law Review* 70; W Howarth, ‘Aspirations and Realities under the Water Framework Directive: Proceduralisation, Participation and Practicalities’ (2009) 21(3) *Journal of Environmental Law* 391; J Scott and J Holder, ‘Law and New Environmental Governance in the European Union’ in G de Búrca and J Scott (eds), *Law and New Governance in the EU and the US* (Hart Publishing, 2006); Scott, note 32 above; and Senden, note 24 above;. It is worth noting that the pieces by Howarth, Korkea-aho and by Scott and Holder concern post-legislative guidance issued by the Commission and Member States in the context of the EU Water Framework Directive, and not guidance issued by an EU agency.

⁴⁰ Scott, note 32 above

⁴¹ And so future work might usefully compare post-legislative guidance with other post-legislative frameworks for rule making (rather than with primary legislation).

⁴² C Kilpatrick, ‘On the Rule of Law and Economic Emergency: The Degradation of Basic Legal Values in Europe’s Bailouts’ (2015) *Oxford Journal of Legal Studies* 1

⁴³ *ibid*, p7

⁴⁴ Those that did not were: FRONTEX; EASO; ECDC; CEDEFOP; EFCA; EUROFOUND; GSA; EIGE; EMCDDA; ENISA; CEPOL; EUROPOL; ETF; EUROJUST; and CdT. It is important to note that some of these agencies did produce guidance, but such was co-legislative (sitting alongside, but not linked to, legislation) or extra-legislative (existing in the place of legislation), rather than post-legislative.

⁴⁵ <http://srb.europa.eu/>

⁴⁶ Article 8(3), Commission Regulation (EU) No 806/2014 [2014] OJ L225/1

future.⁴⁷ With the final two agencies, the EEA and EU-OSHA, it was not at all clear whether they produce their *own* post-legislative guidance that bears *their own* names (as opposed to guidance that they use that is issued by, say, the Commission).⁴⁸ Email queries to these two agencies for clarification had similarly unclear responses.⁴⁹

Among the 14 EU agencies that produced post-legislative guidance, practice differed significantly. Four each produced only one or two guidance documents.⁵⁰ Eight produced considerably more, ranging from 18 (BEREC) to 163 (CPVO) guidance documents.⁵¹ The remaining two regulators, EMA and ESMA, both appear to publish a large number of guidance documents but the exact figure is hard to pin down. With EMA, 1,509 documents are returned when using the ‘Search Guidelines’ function on the ‘Human Regulatory’ part of website, but many of these appear to be the same document authored and published by EMA but in different EU languages. The same problem occurs with ESMA, where 363 ‘Guidelines and Recommendations’ are found when searching the website by document type: ‘Guidelines and Recommendations.’⁵² Issues of access are discussed below.

Where agencies produced guidance documents, these varied significantly in length. Some were under 10 pages; most were between 15 and 60 pages long. However, a number were considerably longer. For example, the EFSA ‘Guidance on Data Exchange’ comprises 173 pages;⁵³ the single OHIM guideline is 605 pages (or 231,473 words) long,⁵⁴ and ECHA’s 21 core guidance documents on REACH amount to more than a million words (almost ten times as long as the text of the underlying Regulation).⁵⁵ While my focus in this paper is not on what functions guidance may serve,⁵⁶ one example of how guidance significantly operationalises legislation is perhaps worth pulling out. Article 29 of the EU’s flagship chemicals regulation REACH contains the bare command to registrants (chemical manufacturers, importers etc) to form a ‘substance information exchange forum’ or SIEF, a mandatory grouping of all registrants of the same substance who are obliged to come together to share chemicals testing data and submit a joint registration dossier containing that data.⁵⁷ REACH contains no other advice on how SIEFs are created or to be run. Instead, there are three key ECHA guidance documents relevant to SIEFs and data generation and assessment: (a) Guidance on Data Sharing (148 pages long);⁵⁸ (b) Guidance on Information Requirements and Chemical Safety Assessment (28 linked guidance documents, amounting to more than

⁴⁷ <http://www.eulisa.europa.eu/AboutUs/WhoWeAre/Documents/eu-LISA%202013%20Activity%20Report.pdf>

⁴⁸ See, for example: <https://osha.europa.eu/en/topics/riskassessment/guidance.pdf>

⁴⁹ A search of the EEA website for ‘guidance’ produces over 60,000 hits. The same search of the EU-OSHA website produced over 40,000 hits. Both websites were vast and challenging to navigate.

⁵⁰ ACER, EMSA, FRA and OHIM

⁵¹ BEREC has 18 guidance documents; CPVO has four guidance documents and 159 ‘technical protocols’; EASA publishes 104 ‘acceptable means of compliance’ and ‘guidance materials’ documents; EBA has 32 ‘Final Products’ plus 54 ‘Related Documents’ under its ‘Guidelines; EIOPA has 27 guidelines plus 9 Opinions; ECHA has 28 ‘Guidance’ documents, 8 Nutshells, 10 factsheets, 16 practical guides and 14 formats; EFSA has 40 guidance documents; and ERA has 11 ‘technical specifications’, one ‘application guide’, 8 ‘specific guides’ plus at least 6 ‘guidance documents’

⁵² These are two agencies where further exploration of their guidance could usefully be done.

⁵³ <http://www.efsa.europa.eu/en/search/doc/1895.pdf>

⁵⁴ <https://oami.europa.eu/tunnel->

web/secure/webdav/guest/document_library/contentPdfs/law_and_practice/trade_marks_practice_manual/WP/P art-A/00-

[editors_note_and_general_introduction/track_change/00_editors_note_and_general_introduction tc_en.pdf](editors_note_and_general_introduction/track_change/00_editors_note_and_general_introduction_tc_en.pdf)

⁵⁵ <http://echa.europa.eu/guidance-documents/guidance-on-reach>

⁵⁶ Instead, see: Vaughan, note 17 above

⁵⁷ Article 29, Council Regulation (EC) 1907/2006 [2006] OJ L33/1

⁵⁸ http://echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf

200,000 words of text across 2,232 pages);⁵⁹ and (c) Guidance for Identification and Naming of Substances (118 pages long).⁶⁰ Of all the elements of REACH, the creation and running of SIEFs is *the* area in which guidance produced by ECHA amplifies the text of the Regulation and shapes the day-to-day operation of the legislation. I have suggested elsewhere that, without this guidance, data generation, assessment and sharing under REACH would fail.⁶¹

There also seems to be a trend in that post-legislative guidance appears to be getting longer. For example, ACER has issued three editions of guidance linked to the REMIT Regulation.⁶² The first edition (December 2011) was 24 pages long; the second edition (September 2012) was 54 pages long; and the third edition (October 2013) is 60 pages long.⁶³ We might view revisions and new editions of post-legislative guidance in two distinct ways: first; we might see such as continuing and comprehensive ‘mission creep’ (expansions in the scope of agency norm making); or second, we might see new editions and updates as part of new governance claims of norm revisability in the light of practical experience. The challenge with the second view is that if, as discussed below, the judiciability of guidance is limited (and it is) then revisions and updates which raise concerns about legitimacy may go unchecked, notwithstanding the overall potential of guidance as a flexible and fluid correcting mechanism to legislation.

Standing back, what we see is widespread but not pervasive production of post-legislative guidance by almost half of the EU’s 33 decentralized agencies, amounting to hundreds of documents and thousands of pages. This is a significant practice, both as regards the exercises of power by EU agencies and as regards the wealth of norms that are yoked onto underlying legislation, and a practice that is under explored.

B. The Grant of Power

EU legislation grants power to EU agencies to issue guidance in three ways: (i) an agency can be obliged to produce guidance on a given, specific topic; (ii) an agency can be given a wide ranging, generic power to produce guidance; or (iii) an agency can be given both a generic power to produce guidance and there can be specific instances set out in the legislation in which guidance is required. The first of these is seen with only one agency, ACER.⁶⁴ The second is seen with six of the EU agencies that produce guidance: BEREC;⁶⁵ EASA;⁶⁶ EBA;⁶⁷ EFSA;⁶⁸ EIOPA;⁶⁹ ERA;⁷⁰ and ESMA.⁷¹ The third is seen with CPVO,⁷² ECHA,⁷³ and SRB.⁷⁴

⁵⁹ <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

⁶⁰ http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf

⁶¹ Vaughan, note 17 above at Chapter 6

⁶² http://www.acer.europa.eu/remit/Pages/ACER_guidance.aspx

⁶³ http://www.acer.europa.eu/remit/Pages/ACER_guidance.aspx

⁶⁴ Article 16(1), Commission Regulation (EU) No 1227/2011 [2011] OJ L326/1

⁶⁵ Article 6(2), Council Regulation (EC) No 1211/2009 [2009] OJ L 337/1

⁶⁶ Article 18(c) and Article 52, Council Regulation No 216/2008 [2008] OJ L79/2

⁶⁷ Article 16(1) Commission Regulation (EU) No 1093/2010 [2010] OJ L331/12

⁶⁸ Article 31(1), Council Regulation (EC) No 178/2002 [2002] OJ L31/1

⁶⁹ Article 16(1), Commission Regulation (EU) No 1094/2010 [2010] OJ L331/48

⁷⁰ Articles 1 and 2, Council Regulation (EC) No 881/2004 [2004] OJ L220/3

⁷¹ Article 16, Commission REGULATION (EU) No 1095/2010 [2010] OJ L331/84

⁷² Articles 36(1)(a) and 56(2), Council Regulation (EC) No 2100/94 [1994] OJ L227

⁷³ See: <http://echa.europa.eu/regulations>

⁷⁴ Articles 8, 12 and 31, Commission Regulation (EU) No 806/2014 [2014] OJ L225/1

There is also a fourth possibility: (iv) that EU legislation does not grant EU agencies any specific or generic powers to issue guidance to third parties, but instead sets out for those agencies other tasks which could, arguably, include guidance production. So, for example, with EMSA, there is no specific reference to guidance or guidelines, but Article 1(2) of its establishing Regulation sets out that the agency is to provide ‘technical, operational and scientific assistance.’⁷⁵ Article 124(2)(a) of the Regulation establishing OHIM sets out that the President of OHIM, ‘shall take all necessary steps, including the adoption of internal administrative instructions and the publication of notices, to ensure the functioning of the Office.’⁷⁶ The OHIM Guidelines are interesting in that they are not addressed to third parties but rather set out how the Office will make decisions and exercise its power when it receives applications for trademark and patent registrations. Other agencies also produce internal guidelines, and disclose that they exist, but do not also make the content of those guidelines public.⁷⁷

This leaves us with the EMA. Here, there is no specific grant of power to the Agency to produce guidance. Rather, in the different pieces of EU legislation on medicines,⁷⁸ it is the Commission that is obliged to produce various guidelines. Where, or how, or if, these mandates have been delegated to the EMA is unclear, despite the guidance on the EMA website reviewed for this paper being published by the EMA under the Agency’s own name. As Chiti comments, ‘The EMA is not expressly entrusted with rulemaking powers by the establishing Regulation. And it seems rather reluctant to interpret its mission in such a way as to engage in the exercise of rulemaking tasks. Yet, it issues technical, scientific and procedural guidance concerning the implementation of the EU pharmaceutical legislative framework.’⁷⁹ In *Commission v UK*, a matter concerning compliance by the UK with an EU Directive on urban waste water treatment, the European Court of Justice (ECJ) commented that, ‘[S]ince the concept of ‘unusually heavy rainfall’ is not defined by Directive 91/271, it is legitimate for the Commission, in carrying out its supervision of compliance with European Union law, to adopt guidelines.’⁸⁰ Despite this, it is not clear whether such legitimacy would extend to an EU agency without some form of mandate in the underlying legislation.⁸¹

For the majority of EU agencies, the underlying legislation says actually very little about the guidance those agencies are allowed to produce. As such, Chiti characterizes the procedural aspects of post-legislative guidance by EU agencies as ‘thin’, and argues that the, ‘the overall tendency is to formalise only a very basic procedural outline.’⁸² The power to produce guidance is often given in the legislation free of limitation, and these agencies enjoy a wide discretion in what and when and how they produce guidance. However, with the EU’s three new financial services regulators, EBA, EIOPA and ESMA, there comes a new, more detailed, way of drafting obligations in relation to agency guidance.⁸³ In the three pieces of

⁷⁵ Council Regulation (EC) No 1406/2002 [2002] OJ L394/1

⁷⁶ Council Regulation (EC) No 6/2002 [2002] OJ L3/1

⁷⁷ Two of the BEREC Guidelines are internal guidelines addressed to BEREC staff/committees. However, these 2 documents are not published for public consumption. See:

http://berec.europa.eu/eng/document_register/subject_matter/berec/regulatory_best_practices/guidelines/4885-internal-guidelines-on-the-operation-of-berec-expert-working-groups

⁷⁸ http://ec.europa.eu/health/documents/eudralex/index_en.htm

⁷⁹ Chiti, note 9 above at pp 97-98

⁸⁰ *Commission v UK*, Case C-301/10 ECLI:EU:C:2012:36, para 61

⁸¹ See, for a recent case on this point: *UK v European Parliament and Council*, C-270/12, ECLI:EU:C:2014:18

⁸² Chiti, note 9 above at p101

⁸³ Though it should be noted that there is some similarity between the Article 16 seen in the underlying EBA, EIOPA and EMSA legislation and Article 52 of Council Regulation No 216/2008 [2008] OJ L79/2 establishing EFSA

legislation establishing the three agencies is the same provision, Article 16.⁸⁴ Unlike other legislative mandates to produce guidance, Article 16 sets out expectations as to consultation, impact assessments, the use of stakeholder groups, articulates a ‘comply or explain’ (or ‘naming and shaming’)⁸⁵ approach to guidance, and introduces an obligation on the Agency to report on compliance. This approach is unique and is not, for example, seen with the EU’s newest agency, the Single Resolution Board. The grant of power to the SRB to produce guidance is as thin, and as lacking in detail as that granted to many of the older agencies.⁸⁶ It seems then that the need for harmonization in the context of EU financial services is special, different and worthy of a new approach in the context of the powers formally granted to those agencies.⁸⁷ It also seems that there is not a marked evolution in how the legislature introduces guidance making powers into EU laws (such that Article 16 represented the ‘best’ modern, reflective approach and would be the standard going forward). In the final part of this paper, I argue that elements of the Article 16 approach might represent good practice that should be adopted across all EU agencies.

C. Bindingness

The following two sections concern the potential bindingness of guidance and the extent to which guidance has, or will come to have, its own hierarchies. These two sections are inextricably linked. It is possible to see bindingness, in the context of post-legislative guidance, as being comprised of two core facets: (i) an obligation on the recipient (state, entity, citizen) to follow that guidance (a contingent duty of the ‘comply or explain’ variety); and/or (ii) an obligation on the guidance maker (here, the relevant EU agency) to follow the practices and procedures that that guidance lays out.⁸⁸ My interest is more with the former facet than the latter, and with the fallacy that because there is no legal obligation to comply with guidance then that guidance is not binding (such that compliance with the underlying legislative norm could be achieved by alternative means). The latter facet raises interesting questions of legitimate expectations, which are discussed in the section that follows on guidance hierarchies. The European Court of Justice has recognized that lack of bindingness is not synonymous with lack of legal effect.⁸⁹ It is perfectly possible to imagine, and to find examples of, heavily prescriptive, very detailed, rigid post-legislative guidance that is comparable to the most complex EU legislative text, and, equally, possible to imagine and to find examples of guidance that is wide, vague and incapable of producing legal effects. As such, I would suggest that what matters is not what the text of the thing says, but whether that text influences or determines the behavior of addressees (whether external – State, entity, citizen – or internal – the agency itself). As such, the developing agency hierarchy in guidance (discussed below) is largely meaningless if addressees view all guidance as the

⁸⁴ This provision is almost identical in each of the three pieces of underlying legislation. The only difference is that Article 16(3) of the EBA Regulation also says, ‘Without prejudice to the powers laid down in Article 35, the competent authority shall, without delay, provide the Authority with all information which the Authority considers necessary for its investigation including as to how the acts referred to in Article 1(2) are applied in accordance with Union law.’ Commission Regulation (EU) No 1093/2010 [2010] OJ L331/12.

⁸⁵ M Busuioc, ‘Rule-Making by the European Financial Supervisory Authorities: Walking a Tight Rope’ (2013) 19(1) *European Law Journal* 111, p118. Where national competent authorities chose the ‘or explain’ route, the relevant EU agency website contains links to the alternative form of guidance and this different approach is discussed in that EU agency’s annual report. What is not clear is whether, say, the Commission takes an active approach to reviewing the ‘or explain’ alternative approaches and/or the EU agency’s own approach to those approaches.

⁸⁶ See Articles 8(3) and 31(1) of Commission Regulation (EU) No 806/2014 [2014] OJ L225/1.

⁸⁷ Busuioc, note 85 above at p112

⁸⁸ I am grateful to the anonymous reviewer for a specific suggestion on these two aspects.

⁸⁹ *Grimaldi v Fonds des maladies professionnelles*, C-322/88, EU:C:1989:4407

same, and equally influential or determinative (although I accept that this supposition requires empirical evidence).

Emilia Korkea-aho opens her book on new governance with the following,

In the comic strip that Kevin Tuma drew for the periodical *Regulation*, a big eyed, bald man stares, with a kind of exasperated expression on his face, at a piece of paper that reads, ‘The Very Big Regulatory Agency of America has issued the following Guidelines: “We Recommend that YOU MUST DO THE FOLLOWING...”’⁹⁰

Scholarship on soft law is preoccupied with the question of bindingness.⁹¹ This is perhaps a by-product of the history of the field. Starting in the 1970s much of the writing on hard law/soft law comes from literature in law and political science on international relations and public international law.⁹² In this area, defining ‘law’ (and, as a corollary, its hard and soft forms) is difficult and soft law in this context is largely (but not exclusively) premised on informality and voluntarism.⁹³ There are a number of scholars who argue that the notion of ‘soft’ law is a contradiction: either law is binding (or hard) or it is not law.⁹⁴ However, Linda Senden has commented, and I would agree, that ‘the distinction binding/non-binding is too black-and-white, too simple’.⁹⁵ I would suggest that a better emphasis than binding/not-binding is found in a presentation given by Niamh Moloney at a January 2014 EBA workshop in which she questions ‘the normative colour of guidance,’⁹⁶ and which allows for a spectrum in the context of whether guidance influences or determines the behavior of addressees.

EU frame the extent to which their guidance is or is not binding in two main ways: direct statements as to bindingness; and through the use of disclaimers. I am interested both in the variety of practices on direct statements and disclaimers, and in what, if anything, those statements and disclaimers mean.⁹⁷ Of the 14 agencies that produce guidance three agencies state, in every guidance document that they produce, that such guidance is not legally binding.⁹⁸ Five agencies sometimes have statements about bindingness and sometimes do not, with no real pattern as to when or why this happens.⁹⁹ Four agencies do not make statements as to bindingness in their guidance documents, but such can be found in higher level FAQs or scene setting approach documents.¹⁰⁰ The remaining two agencies make no

⁹⁰ E Korkea-aho, *Adjudicating New Governance: Deliberative Democracy in the European Union* (Routledge, 2015) p1

⁹¹ Senden, note 23 above at p112

⁹² By way of a starting point into this literature, see the special issue of *International Organisation* (2000(3)).

⁹³ JJ Kirton and MJ Trebilcock, ‘Hard Choices, Soft Law: Voluntary Standards in Global Trade’ in JJ Kirton and MJ Trebilcock (eds), *Hard Choices, Soft Law: Voluntary Standards in Global Trade, Environment and Social Governance* (Ashgate 2004) p9

⁹⁴ See, for example: P Weil, ‘Towards Relative Normativity in International Law?’ (1983) 77(3) *American Journal of International Law* 413; J Klabbers, ‘The Undesirability of Soft Law’, (1998) 67(4) *Nordic Journal of International Law* 381; H Hillelgenberg, ‘A Fresh Look at Soft Law’, (1999) 10(3) *European Journal of International Law* 499

⁹⁵ Senden, note 23 above at p112

⁹⁶ <http://www.eba.europa.eu/documents/10180/498024/Presentation+++Niamh+Moloney.pdf>

⁹⁷ The European Ombudsman has considered the nature of disclaimers in a number of recent rulings. For an account of these, see: M Lee, ‘Accountability and Co-Production Beyond Courts: The Role of the European Ombudsman’ (Working Paper for ‘Regulating Risks in the EU: The Co-production of Expert and Executive Power, Amsterdam, 21-22 May 2015)

⁹⁸ ACER; EMSA and OHIM

⁹⁹ BERC; EBA; EFSA; ERA; ESMA

¹⁰⁰ EASA; ECHA; EIOPA; EMA

statements as to bindingness.¹⁰¹ The language used in some of the BEREC ‘Guidelines’ is particularly perplexing: ‘This guidance is not legally binding. Nevertheless, [national regulatory authorities] are required to take the utmost account of it.’¹⁰² Seven agencies set out that, while the guidance is not binding, departures from the guidance need to be justified.¹⁰³ One of the EASA FAQs articulates the reason for complying with guidance as follows:

If you follow the EASA AMC there is a presumption that you comply with the rules, and competent authorities will recognise that compliance without the need for any further demonstration of compliance from your side. If you choose to use alternative means to comply with the rule, you will need to demonstrate compliance with the rule to your competent authority. The burden of proof of compliance rests fully with you.¹⁰⁴

Similarly, the EMA states that, ‘The Agency strongly encourages applicants and marketing-authorisation holders to follow these guidelines. Applicants need to justify deviations from guidelines fully in their applications at the time of submission.’¹⁰⁵ Thus we have guidance, which is not binding, but deviations from which need to be disclosed and justified. In *Momentive Specialty Chemicals*, ECHA had rejected the appellants’ registration dossier as inadequate because Momentive had failed to comply with ECHA’s guidance. The ECHA Board of Appeal commented that,

...in not following the available guidance the Appellant did not avail itself of a tool designed to help registrants to prepare and submit their proposals in an effective way. The Board of Appeal observes that in so doing the Appellant may have required additional effort to justify its case compared with following the approach described in the guidance.¹⁰⁶

This suggests that while ECHA’s guidance is not necessarily binding on third parties, in that registrants are not obliged to follow it, where third parties use standards or take approaches *different* to those set out in the agency’s guidance, ‘additional effort’ will be required of them to justify taking that path. This also suggests that ECHA’s guidance may, in practice, only really be semi-soft (and so acts as another challenge to the commonly understood hard law/soft law divide, discussed earlier). I would argue that, in practice, the same can be said of much of the other guidance produced by other EU agencies. As discussed above, the three new financial services agencies (EBA, EIOPA and ESMA) each have a ‘comply or explain’ approach to guidance, which is discussed in the 2013 EIOPA Annual Report as follows: ‘Comply-or-explain for Guidelines issued during 2013 - All national competent authorities (NCAs) reported their compliance or intention to comply with the referred Guidelines within

¹⁰¹ CPVO; and FRA

¹⁰²

http://berec.europa.eu/eng/document_register/subject_matter/berec/regulatory_best_practices/guidelines/1015-berec-guidelines-on-the-application-of-article-3-of-the-roaming-regulation-wholesale-roaming-access - my emphasis

¹⁰³ BEREC; EFSA; EBA, EIOPA and ESMA; EASA; EMA

¹⁰⁴ <https://www.easa.europa.eu/the-agency/faqs/acceptable-means-compliance-amcs-and-alternative-means-compliance-altmocs>

¹⁰⁵

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000043.jsp&mid=WC0b01ac05800240cb – this is ‘comply or explain’ model is also seen in guidance issued by BEREC and EFSA.

¹⁰⁶ *Momentive Specialty Chemicals v ECHA*, (ECHA Board of Appeal, Case A-006-2012, 13 February 2014) para 61

two months.’¹⁰⁷ So, while it is possible to demonstrate compliance *other* than by the means set out in guidance, the data from the sphere of EU financial services regulation suggests otherwise.

Two of the agencies under review have specific disclaimers in relation to their guidance. The single set of guidelines produced by EMSA details that, ‘Under no circumstances shall EMSA or any of the other contributors be liable for any loss, damage, liability or expense incurred or suffered that is claimed to have resulted from the interpretation and the use of the information presented in these Guidelines.’¹⁰⁸ Similarly, all of ECHA’s guidance documents contain a ‘Legal Notice’ in the following terms, ‘Users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.’¹⁰⁹

The landscape drawn in this section is full of contradictions: guidance is not binding, but adherence is evidence of compliance, departures may need to be highlighted and justified, and there is some empirical data that everyone in the real world does what the guidance says. Some, but not all, of the EU agencies that produce guidance include statements about the binding nature of that guidance and that, even when agencies do include such statements, they do not always do so consistently. While this is interesting in terms of on-the-ground variation, and so adds some definition to the map of guidance practice, two matters are unclear. The first is why some agencies, in some instances, include statements on bindingness. Is this simply a drafting preference of the particular agency executive charged with drawing up the guidance? Or is it something more? The second matter is whether these statements, and disclaimers, change the nature of the underlying document. In *N.V. Elektriciteits* (discussed further below), ECHA’s Board of Appeal found that ECHA’s FAQs created legitimate expectations for registrants.¹¹⁰ Can, or should, a disclaimer (either on a document or via a website legal notice) operate to frustrate those expectations? In a case before the ECJ disputing when the time limit for bringing proceedings began (publication on the internet or publication via the Official Journal), Advocate General Cruz Villalon commented that, ‘For a website to be regarded as properly fulfilling an obligation to publish, in the strict sense, it must be technically capable of ensuring that a disclaimer such as the one covering the ECHA website is, at least for part of the content of that site, plainly unnecessary.’¹¹¹ Given this, I would suggest that the disclaimers used by the EU agencies are meaningless, and arguably void, in situations where the underlying legislation mandates the agency to produce guidance.

D. Hierarchy in Guidance?

Is a ‘Guideline’ the same as a document headed ‘Guidance’? Are the norms which make up a ‘Technical Guide’ any different to the norms in an ‘Opinion’? Should a third party be more inclined to follow what is in a ‘Nutshell’ and/or a ‘Quick Guide’ and/or the answer to a ‘FAQ’? There are perhaps two replies to these questions. The first is that what counts is substance, not form, and so it is irrelevant what any given document is titled. In *France v*

¹⁰⁷ <https://eiopa.europa.eu/publications/annual-reports>

¹⁰⁸ EMSA, ‘EU States Claims Management Guidelines’ (December 2012) p5

¹⁰⁹ The exact wording is not identical in each ECHA guidance document, as the agency is responsible for multiple EU regulatory regimes. All of the guidance documents can be found here:

<http://echa.europa.eu/support/guidance>

¹¹⁰ *N.V. Elektriciteits v ECHA* (ECHA Board of Appeal, Case A-001-2010, 10 November 2011) paras 40, 88-94 and 168

¹¹¹ *PPG and SNF SAS v ECHA*, C-625/11, EU:C:2013 (not yet reported), para 34. I am grateful to Kenneth Armstrong for bringing this case to my attention.

Commission, the ECJ noted that, ‘The Court has consistently held that an action for annulment is available in the case of all measures adopted by the institutions, whatever their nature or form, which are intended to have legal effects.’¹¹² The second, alternative, reply is that questions as to form and substance only really become engaged in specific contexts – that is, when those documents are adjudicated – and that, for the overwhelming majority of guidance documents, the likelihood of adjudication is very small indeed. As such, there are really no satisfactory or meaningful answers to these questions and thus those to whom they are addressed would need, in the real world, to muddle through them as best as they are able.¹¹³

When we look at the diversity of post-legislative practice among these 14 EU agencies, we see a wide variety of titles given to documents which all, on their face, perform similar guidance functions.¹¹⁴ These are set out in Table 1 below.

Table 1: Agency Guidance Formats/Titles

Agency	Guidance Formats/Titles
ACER	‘Guidance’; ‘Q&As’
BEREC	‘Guidance’; ‘Common Approaches’; ‘Guidelines’; ‘Guides’ ‘Methodologies’; ‘Advices’;
CVPO	‘Guidance’; Notes’; ‘General Instructions’; ‘Technical Protocols’
EASA	‘Guidance Materials’; ‘Acceptable Means of Compliance’; ‘FAQs’
ECHA	‘Guidance’; ‘Nutshells’; ‘Factsheets’; ‘Practical Guides’; ‘Formats’; ‘FAQs’
EFSA	‘Guidance’; ‘Opinions’; ‘Statements’; ‘Reasoned Opinions’; ‘Conclusions’; ‘Reports’
EIOPA	‘Guidance Notes’; ‘Guidelines’; ‘Opinions’; ‘One Minute Guides’; ‘FAQs’
EMSA	‘Guidelines’; ‘Manuals’; ‘Inventories’
ERA	‘Guidance; ‘Technical Specifications for Interoperability’; ‘Application Guide’; ‘Specific Guides’
EBA	‘Guidelines’
EMA	‘Guidelines’
ESMA	‘Guidelines’
OHIM	‘Guidelines’

The breadth of this miscellany (26 different titles) is striking. There does not appear to be any significant correlation with potential different audiences for the guidance,¹¹⁵ nor with the different grants of power to the different agencies. Four examples from the 14 agencies that produce guidance are worth drawing out. The 27 EIOPA ‘Guidelines’ have their own Q&A section which, in turn, then has its own ‘guidance notes’, and one (and only one) of the EIOPA ‘Guidelines’ has a linked ‘One Minute Guide’. This Russian doll of post-legislative practice is also seen with ECHA (where a number of the agency’s ‘Guidance’ documents have linked ‘Nutshells’ and ‘Factsheets’ that summarise the ‘Guidance’ in a shorter form); and with ERA (which publishes Technical Specifications for Interoperability (TSIs)

¹¹² *France v Commission*, Case C-57/95, ECLI:EU:C:1997:164, para 7. See also Scott, note 32 above at p329

¹¹³ There is a real empirical gap in the work on post-legislative guidance, a gap which could be usefully filled.

¹¹⁴ For a detailed account of these functions, see: Vaughan, note 17 above

¹¹⁵ Save, perhaps that Opinions tend to be issued to the Commission (or other EU body)

accompanied by one general ‘Application Guide’ and eight, linked ‘Specific Guides’). The ERA makes it clear that the ‘Specific Guides’ provide guidance and help to explain the guidance in the TSIs.¹¹⁶ ECHA labels everything save for the core guidance documents as ‘quasi guidance’, with the intent that these are ‘in simple terms’ and particularly intended for SMEs.¹¹⁷ While the meaning of ‘quasi guidance’ is tautologous (you only sort of have to comply with something you don’t have to comply with), there is an implicit hierarchy of norms in the guidance ECHA produces. This is also seen in case law, in a decision by ECHA’s Board of Appeal concerning FAQs published by the agency. In *N.V. Elektriciteits*, the Board found that ECHA’s FAQs created legitimate expectations for registrants because of the need for registrants to know their legal obligations and because of the precision of the relevant FAQs.¹¹⁸ The Board went on to comment on the differences between the 21 guidance documents produced by ECHA and the Agency’s FAQs:

The legal nature of the FAQs needs to be distinguished from the REACH Guidance, which are drafted and issued in close co-operation with the stakeholders. Compared to the REACH Guidance, the legal nature of the FAQs is different and less complex as the Agency alone decides on the contents of the FAQs and their purpose is to directly inform registrants of the Agency’s administrative practice.¹¹⁹

Exactly how the ‘legal nature’ of FAQs is ‘different’ to other forms of ECHA guidance is not elaborated on by the Board. One possible explanation is that the Board was of the view that ECHA ‘Guidance’ was binding on addressees whereas the FAQs only bound the agency itself (in situations where the FAQs were sufficiently precise). The EMA website details that its Committee for Medicinal Products for Human Use issues ‘scientific guidelines’ and then sets out, under a heading of ‘Related Document Types’ that,

Historical documents such as ‘notes for guidance’ are included in the compilation where they have the regulatory status of a guideline. Following the implementation of the procedure on EU guidelines, however, the use of these terms has been discontinued. Documents that do not have the status of a guideline, such as position papers, reflection papers or question-and-answer documents, continue to be published in the relevant working-party folders.¹²⁰

But what, exactly, is the ‘regulatory status of a guideline’? Differentiation within guidance requires us to take a hard look at what counts (and does not count) for a variety of purposes in shaping the operationalization of legislation. The ECHA Board of Appeal accepted that FAQs created legitimate expectations for applicants, which is important given just how many ECHA FAQs there are.¹²¹ Would the same be said of all of the other types of guidance document that ECHA or other agencies produce? Is there a point at which guidance stops creating legitimate expectations, or is everything that an agency puts out which impacts on

¹¹⁶ <http://www.era.europa.eu/Core-Activities/Interoperability/Pages/TSI-Application-Guide.aspx>

¹¹⁷ ECHA, ‘General Report 2011’ (ECHA, 2011) p46 – see:

https://echa.europa.eu/documents/10162/13560/mb_06_2012_general_report_2011_final_en.pdf

¹¹⁸ *N.V. Elektriciteits v ECHA*, note 110 above, paras 40, 88-94 and 168

¹¹⁹ *Ibid*, para 56

¹²⁰

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000043.jsp&mid=WC0b01ac05800240cb

¹²¹ As of 17 April 2015, there were 984 separate FAQ answers on the ECHA website. See:

<http://echa.europa.eu/support/qas-support/search-qas>

the operation of underlying legislation capable of creating expectations that are legitimate? There is no clear answer to this in the existing case law. Certainly, the leading EU cases on legitimate expectations concern what might be thought of as first order or standard forms of guidance: guidelines, decisions etc, all of which *are* capable of giving rise to legitimate expectations.¹²² Kenneth Armstrong frames new governance as seeking to provide a legal response to the proliferation of modes of governance and to explain how these changes signal, ‘the decline of a traditional world of hierarchical governance.’¹²³ I wonder whether, in the proliferation of multiple forms and formats of guidance, we are now seeing a less traditional, but potentially equally hierarchical, form of governance in the post-legislative phase.

E. Access and Participation

Conducting much of the research for this paper was painful, and protracted, because of the poor quality of the websites of many of the EU’s decentralized agencies.¹²⁴ This is a function both of navigation – how easy it is to move around the site; how it is laid out etc – and where and how guidance documents are located on those sites. Some agencies have ‘Document Libraries’ on their websites, others have ‘Publications’ sections or take a thematic approach and group documents under different sub-pages. The practical difficulties in finding documents on those websites that are, or might be, guidance are not insignificant. By contrast, all the agencies had a ‘Legislation’ section that was relatively easy to locate.

Not all of the guidance produced by the EU agencies is available in all of the EU’s official languages. Practice varies significantly. Some guidance documents are available only in English;¹²⁵ some in a handful of EU languages;¹²⁶ and others (a minority) in all of the EU’s official languages.¹²⁷ Claire Kilpatrick argues that, ‘the Rule of Law requires that major normative sources should be available in the languages of those subject to them.’¹²⁸ Are then guidance documents ‘major normative sources’? As we saw in Part II of this paper, some of the guidance documents are significant both in length and in number, and my other work on ECHA has shown that its guidance documents effectively operationalize the Regulation in a number of different areas.¹²⁹ However, almost all of the guidance documents produced by EU agencies are available only in a minority of the official languages of the EU.¹³⁰ There are practical translation issues to be overcome, and linked challenges of funding and agency staffing, but it is conceivable that the EU courts would consider guidance published only in, say, English, an unfair competitive advantage to entities based in the UK and Ireland (and/or with English speaking employees).¹³¹

As with legislation, one’s interest in guidance might extend beyond its current form to an interest in previous iterations, and how that guidance has changed over time. Very few,

¹²² For a review of this case law, see: P Craig, *EU Administrative Law* (OUP, 2012) Ch 18

¹²³ Armstrong, note 19 above, 251

¹²⁴ The websites of the following agencies are particularly poorly designed and hard to use: EU-OSHA; EEA; GSA; ERA; OHIM; and CdT. The websites of the EASA and EBA, however, are very slick and navigable.

¹²⁵ For example, the CPVO Protocols

¹²⁶ For example, the ERA guidance and the single set of OHIM ‘Guidelines’

¹²⁷ For example, some of ECHA’s and EIOPA’s guidance documents

¹²⁸ Kilpatrick, note 42 above at p29

¹²⁹ Vaughan, note 17 above

¹³⁰ See, further, on translation: *Polska Telefonia v Prezes Urzedu Komunikacji Elektronicznej*, C-410/09, ECLI:EU:C:2010:395; and O Stefan, ‘European Union Soft Law: New Developments Concerning the Divide between Legally Binding Force and Legal Effects’ (2012) 75 MLR 879

¹³¹ *Italy v Commission*, C-566/10P, EU:C:2012:752. As discussed in Kilpatrick, note 42 above at p18

however, of the EU's agencies allow this sort of enquiry to be undertaken easily.¹³² ACER is unusual in that you can see, within its guidance, a redline document showing tracked changes to the guidance over time.¹³³ OHIM does the same for its guidelines.¹³⁴ On the ERA website, previous versions of some of its guidance documents are to be found alongside the current versions, together with an overview of the chronology of all the 'Technical Specifications' (including those that have been repealed).¹³⁵ However, these are isolated examples.

What is also concerning is the lack of specificity (and clarity) on how the guidance documents are produced, and who has input into them. We might imagine participation along a spectrum in which mere consultation is at one end, full public participation is at the other, and range of forms of 'collaborative governance' in the middle.¹³⁶ For most of the agencies under review, it is not clear where on this spectrum their processes for guidance production (if, indeed, such processes are formalized) lie. ACER has a public 'Guidance Note on Consultations' but this note, oddly, does not refer to ACER guidance.¹³⁷ Instead the ACER guidance Q&As set out, in a rather laconic fashion, that, 'The non-binding Guidance is updated from time to time to reflect changing market conditions and the experience gained by the Agency and NRAs in the implementation of REMIT, including through the feedback of market participants and other stakeholders.'¹³⁸ The 'Consultation' page of the BEREC website sets out that the agency 'may' hold a public hearing, consultation periods last 20 days and the agency Board has the power to decide when, or if, a public consultation is needed.¹³⁹ CPVO is completely silent on how, or if, consultation takes place on its guidance documents. EASA is mandated by its founding legislation to consult the Member States and 'interested parties' when drawing up guidance,¹⁴⁰ but the Regulation is silent on exactly how this should happen.

In some of the 'Explanatory Notes' that sit alongside EASA's guidance documents we see short comments on how those documents came to be: 'The content of this Decision is the result of an extensive consultation process involving authorities, associations, operators and aviation experts',¹⁴¹ but we are told no more about the relevant authorities, associations, operators and experts. With OHIM, it is evident that consultation happens, but it is totally opaque as to who actually gets involved, how they know to get involved, how their views are taken into account, how disagreements are managed etc.¹⁴² A Guidance Consultation

¹³² It would be possible to ask the respective agencies for copies of previous guidance versions, or to put in a more formal right to information request.

¹³³

http://www.acer.europa.eu/remit/Documents/Comparison%20of%201st%20and%202nd%20edition%20of%20ACER%20Guidance_final.pdf

¹³⁴ <https://oami.europa.eu/ohimportal/en/manual-of-trade-mark-practice>

¹³⁵ <http://www.era.europa.eu/Core-Activities/Interoperability/Pages/TechnicalSpecifications.aspx>

¹³⁶ M Lee, 'The Ambiguity of Multi-Level Governance and (De-)Harmonisation in EU Environmental Law', (2012) 15 *Cambridge Yearbook of European Legal Studies* 357, p361

¹³⁷

http://www.acer.europa.eu/remit/QandA/Documents/Updated%202nd%20edition%20QandA%20on%20REMIT_FINAL.pdf

¹³⁸

http://www.acer.europa.eu/remit/Documents/REMIT%20ACER%20Guidance%203rd%20Edition_FINAL.pdf

¹³⁹ http://berec.europa.eu/eng/news_consultations/

¹⁴⁰ Article 52, Council Regulation No 216/2008 [2008] OJ L79/2

¹⁴¹ <https://www.easa.europa.eu/system/files/dfu/ED%20Decision%202012-015-R%20-%20Explanatory%20Note.pdf>

¹⁴² See, for example: https://oami.europa.eu/tunnel-web/secure/webdav/guest/document_library/contentPdfs/law_and_practice/trade_marks_practice_manual/WP/P art-A/00-editors_note_and_general_introduction/00_editors_note_and_general_introduction_en.pdf

Procedure was first adopted by ECHA's Management Board in 2008.¹⁴³ However, much of the ECHA consultation is closed in that it involves experts 'whose nominations have been received by a specified deadline'¹⁴⁴ and who are then formed into partner expert groups (PEGs).¹⁴⁵ The ECHA website does not detail lists of experts within PEGs formed as part of previous consultations on guidance. As noted above, the EBA, EIOPA and ESMA are each required, under their foundational legislation, to consult. EIOPA's 'Statement of Consultation Practices' seems to be all things to all people – we will consult various stakeholders and have a 3 month consultation period – but does not say *when* formal consultation will take place, or what for.¹⁴⁶

In their work on the role of private actors in EU regulation, Carolyn Abbott and Maria Lee make three suggestions for reform: '(i) consistent benchmarks should be developed for the reception of outsider contributions within decision-making processes; (ii) the identity or (at least) affiliation of those participating in a decision-making process should be publicly available; and (iii) regulatory, or public regarding, scrutiny of the contributions of economic actors should be strengthened.'¹⁴⁷ I would suggest that the above review provides additional support for these reforms. Legitimacy is commonly understood in EU law in terms of 'inputs' and 'outputs' (that is, the processes that lead up to the act, and the quality of the end product).¹⁴⁸ What we see with the production of guidance by EU agencies is that while there may be robust processes in place, these are, in the majority of instances, not public. Similarly, where those processes are made public, they lack detail and substance.

III. EU JURISPRUDENCE ON GUIDANCE

Joanne Scott and David Trubek have suggested that the EU courts have responded to shifts towards newer forms of governance in a variety of ways: thwarting experiments in new governance; ignoring those experiments; distorting new governance; or seriously engaging with it.¹⁴⁹ In later work, Tamara Hervey argues that the relationship between the EU courts and new governance operates along a spectrum ranging from, 'mutual ignorance; through separation, either with hierarchy or in parallel; to hybrid forms of mutual transformation.'¹⁵⁰ It is at this furthest end of the spectrum that courts are, 'open to being persuaded as to the normative worth of diverse processes born of the diverse experiences of governance.'¹⁵¹ Such openness, as we will see below, has been limited to date in the context of post-legislative guidance.

Judicial review by the EU courts of post-legislative guidance may occur in one of two ways: either via a direct action under Article 263 TFEU, or via preliminary references made to the EU courts by Member State courts under Article 267 TFEU. However, preliminary

¹⁴³ ECHA, 'General Report 2009' (Helsinki, 2009) section 1.5. Later versions of the Procedure were published in 2011 and 2013.

¹⁴⁴ It is not clear what this deadline is or how it is disseminated.

¹⁴⁵ ECHA, note 145 above at p5

¹⁴⁶ https://eiopa.europa.eu/Publications/Statements/Public_Statement_Consultations_Practices.pdf

¹⁴⁷ Abbot and Lee, note 35 above at p28

¹⁴⁸ VA Schmidt, 'Democracy and Legitimacy in the European Union Revisited: Input, Output and 'Throughput' (2013) 61(1) *Political Studies* 2. This paper is not the place to assess the output legitimacy of the guidance produced by the EU's agencies. In my work on EU chemicals regulation, I found very few instances, across the thousands of pages of guidance produced by ECHA, where I had concerns as to the end product of the agency's norm making. See: Vaughan, note 17 above, Chapters 5-8

¹⁴⁹ Scott and Trubek, note 29 above at p9ff

¹⁵⁰ Tamara Hervey, 'Adjudicating in the Shadow of the Informal Settlement?': The Court of Justice of the European Union, "New Governance" and Social Welfare' (2010) 63 *Current Legal Problems* 114, 138

¹⁵¹ J Scott and S Sturm, 'Courts as Catalysts: Re-Thinking the Judicial Role in New Governance' (2007) 13(3) *Columbia Journal of European Law* 565, p591

references happen infrequently for a variety of reasons.¹⁵² Acts adopted by EU agencies are acts of an institution of the EU.¹⁵³ As such, guidance produced by the EU's 33 decentralised agencies should, in theory, be justiciable. The more challenging hurdle is whether those guidance documents can be considered 'acts...intended to produce legal effects' for the purposes of Article 263. In her review of case law in this area, Joanne Scott sets out that Commission Communications, Commission Internal Instructions and a Commission Code of Conduct have all formed the subject matter of admissible actions for judicial review.¹⁵⁴ She argues that there are three situations in which post-legislative guidance may have legal effects (and thus be amenable to review by the EU courts).¹⁵⁵ The first is where guidance is construed as introducing new obligations and adding to the relevant EU legislation; the second situation is where guidance sets out how an EU institution will exercise its discretionary and supervisory powers; and the third is where certain measures, through express statement in legislation or via implication, may be binding on Member States.

While, as noted above, many guidance documents are at pains to clearly state that they are not legally binding, Scott argues that 'non-binding should not be equated with an absence of (legal) effects and careful, contextual analysis is required to assess and evaluate their nature and extent.'¹⁵⁶ The practical challenge, however, for the majority of EU agency guidance being amenable to judicial review is in whether the EU courts would consider that the advice given was simply 'fleshing out' or making more explicit existing legislative obligations (which has previously been said not to be reviewable),¹⁵⁷ or whether that guidance added to the underlying legislation (which would open the guidance up to review). As set out above in Part II, the real world 'fleshing out' of EU legislation via guidance issued by EU agencies is thousands of pages long. If the EU courts exclude such documents from their purview, they (wrongly) push aside a significant portion of the norms that operationalize a wide number of EU legislative texts.

Existing EU jurisprudence shows some acceptance that post-legislative guidance norms can bind the issuer,¹⁵⁸ that these norms can both help in the interpretation of, and can act as a supplement to, legally binding EU rules (to the extent that national courts can reliably follow them);¹⁵⁹ and that such guidance can assist with the uniform and effective application of EU law.¹⁶⁰ However, the cases on post-legislative norms (compared to other, non-yoked forms of soft law) are few in number,¹⁶¹ and most of the substantial commentaries are seen in the opinions of the Advocates General (and not in the rulings of the EU courts). It is hoped that the map of post-legislative practice offered up in this paper will serve as justification for a much closer look by the EU courts at these norms. Such, however, depends greatly on those norms being put forward (via direct actions or preliminary references) for adjudication. There is little evidence to suggest this is happening. As such, the EU courts acting as 'catalysts',

¹⁵² For an overview of why this is so, see: V Heyvaert, J Thornton and R Drabble, 'With reference to the environment: the preliminary reference procedure, environmental decisions and the domestic jury' (2014) *LQR* 413

¹⁵³ *Sogelma v EAR*, C-415/07, EU:C:2009:220

¹⁵⁴ Scott, note 32 above at p339

¹⁵⁵ Scott, note 32 above at pp 340-342

¹⁵⁶ Scott, note 34 above at p331

¹⁵⁷ *France v Commission*, C-325/91, EU:C:1993:3283, para 14

¹⁵⁸ *Expedia Inc v Competition Authority*, C-226/11, EU:C:2012:795, *Germany v Commission*, C-288/96, EU:C:2000:537; *Grimaldi*, note 89 above

¹⁵⁹ Opinion of Advocate General Ruiz-Jarabo in *Lodato Gennaro & C. SpA v INPS and SCCI*, C-415/07 EU:C:2009:220, point 3; *Chemische Fabrik Kreussler* C-308/11, EU:C:2012:548

¹⁶⁰ *BP Chemicals Ltd v Commission*, T-184/97, EU:T:2000:217, para 64

¹⁶¹ Scott, note 32 above; Korkea-aho, note 39 above. There is more, generic case law on the use of soft law instruments, but the cases on the situations where soft norms have yoked to hard legislation are much fewer in number.

creating and prompting ‘occasions for normatively motivated and accountable inquiry and remediation by actors involved in new governance processes’ seems unlikely.¹⁶²

IV. A WAY FORWARD?

This paper has offered up a map of post-legislative guidance practice among the EU’s decentralized agencies. Its findings are summarised in Table 2 below.

Table 2: Post-Legislative Guidance Among EU Agencies

Guidance Production	Widespread and significant, but not pervasive. 14 of the 33 EU’s decentralised agencies produce self-authored guidance.
Volume & Length	Varied. From one or two guidance documents (per agency) to hundreds of guidance documents; and from a handful of pages (per guidance document) to hundreds of thousands of words.
Access	Poorly designed and hard to navigate websites: lack of consistency in where guidance documents are housed (under ‘Publications’, ‘Document Libraries’, ‘Documents’ etc).
Formats	A miscellany of titles: 26 different names for documents which each appear to be post-legislative self-authored agency guidance.
Hierarchy	An emerging, but unclear, hierarchy of sorts in post-legislative norms: Guidance/Guidelines > Guidance Notes > One Minute Guides/Nutshells > FAQs/Q&As.
Bindingness	Contradictory messages: guidance is not legally binding, but adherence is evidence of compliance, departures may need to be highlighted and justified, and there is some empirical data that everyone in the real world does what the guidance says.
Participation & Consultation	An inconsistent and lackadaisical approach.

This map suggests a level of differentiation that is so ill thought out, and so ad hoc, so lacking in foresight and oversight, as to be dysfunctional. At the same time, the lack of engagement by the EU courts with these norms suggest that the site of opportunity for a way forward in this area lies other than with the judiciary. What then should be done? In their work on the role of economic actors in EU law, Abbott and Lee call for consistency in approach and suggest that this ‘may seem to speak for the desirability of something along the lines of a “general administrative law” for the EU.’¹⁶³ I would suggest that something similar could usefully be deployed in the context of post-legislative guidance, either by the Commission or by the EU agencies acting in concert to draw up a code of good administrative practice on guidance that draws on existing approaches by exemplar agencies.¹⁶⁴ This fits in with wider calls for a review of the future of EU agencies. In her work in this area, Ellen Vos has argued

¹⁶² Scott and Sturm, note 151 above

¹⁶³ Abbot and Lee, note 35 above at p28

¹⁶⁴ I would suggest that the ERA, EFSA, ECHA, EBA, ESMA and EIOPA approaches to guidance would be useful starting points.

that, ‘the constitutional disregard of agencies in Article 291 TFEU underlines the uncomfortable position of agencies operating in the shadow of hierarchy.’¹⁶⁵

The post-legislative phase is an important and underexplored site of EU norm making, which raises challenging rule of law questions of clarity, constancy, legitimacy, participation and promulgation.¹⁶⁶ A study such as that offered up in this paper shows that, ‘the adoption of EU legislation is the beginning rather than the end of a process.’¹⁶⁷ My exploration of post-legislative practices highlights the messy, challenging, differentiated worlds of how power and authority are used, constructed and operationalized in the EU. In the proliferation of multiple forms and formats of guidance, we arguably see a less traditional, but potentially equally hierarchical, form of governance in the post-legislative phase. Indeed, I would go so far as to argue, and would use this paper as evidence, that we may need to seriously reconsider, and reframe, the boundaries of law to account for the breadth and depth of post-legislative guidance practice.

¹⁶⁵ E Vos, ‘EU Agencies: Features, Framework and Future’ (Maastricht Faculty of Law Working Paper 2013/3) p35

¹⁶⁶ L Fuller, *The Morality of Law* (Yale University Press, 1969)

¹⁶⁷ Armstrong, note 14 above at p6

APPENDIX 1 – THE EU’S DECENTRALIZED AGENCIES

1. Agency for the Cooperation of Energy Regulators (ACER)
2. Body of European Regulators for Electronic Communications (BEREC)
3. Community Plant Variety Office (CPVO)
4. European Agency for Safety and Health at Work (EU-OSHA)
5. European Agency for the Management of Operational Cooperation at the External Borders (FRONTEX)
6. European Agency for the operational management of large-scale IT systems in the area of freedom, security and justice (eu-LISA)
7. European Asylum Support Office (EASO)
8. European Aviation Safety Agency (EASA)
9. European Banking Authority (EBA)
10. European Centre for Disease Prevention and Control (ECDC)
11. European Centre for the Development of Vocational Training (Cedefop)
12. European Chemicals Agency (ECHA)
13. European Environment Agency (EEA)
14. European Fisheries Control Agency (EFCA)
15. European Food Safety Authority (EFSA)
16. European Foundation for the Improvement of Living and Working Conditions (EUROFOUND)
17. European GNSS Agency (GSA)
18. European Institute for Gender Equality (EIGE)
19. European Insurance and Occupational Pensions Authority (EIOPA)
20. European Maritime Safety Agency (EMSA)
21. European Medicines Agency (EMA)
22. European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
23. European Network and Information Security Agency (ENISA)
24. European Police College (CEPOL)
25. European Police Office (EUROPOL)
26. European Railway Agency (ERA)
27. European Securities and Markets Authority (ESMA)
28. European Training Foundation (ETF)
29. European Union Agency for Fundamental Rights (FRA)
30. Office for Harmonisation in the Internal Market (OHIM)
31. Single Resolution Board (SRB)
32. The European Union’s Judicial Cooperation Unit (EUROJUST)
33. Translation Centre for the Bodies of the European Union (CdT)