Maastricht University

European Union soft law by agencies: An analysis of the legitimacy of their procedural frameworks

Citation for published version (APA):

Rocca, P., & Eliantonio, M. (2020). European Union soft law by agencies: An analysis of the legitimacy of their procedural frameworks. In M. de Bellis, G. della Cananea, & M. Conticelli (Eds.), *EU executive governance: Agencies and procedures* (pp. 177-203). Giappichelli.

Document status and date:
Published: 01/01/2020

Document Version:
Publisher's PDF, also known as Version of record

Document license:
Taverne

Please check the document version of this publication:

• A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
• The final author version and the galley proof are versions of the publication after peer review.
• The final published version features the final layout of the paper including the volume, issue and page numbers.

Link to publication

General rights
Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

• Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
• You may not further distribute the material or use it for any profit-making activity or commercial gain
• You may freely distribute the URL identifying the publication in the public portal.

If the publication is distributed under the terms of Article 25fa of the Dutch Copyright Act, indicated by the “Taverne” license above, please follow below link for the End User Agreement:

www.umlib.nl/taverne-license

Take down policy
If you believe that this document breaches copyright please contact us at:

repository@maastrichtuniversity.nl

providing details and we will investigate your claim.

Download date: 24 May. 2022

Part III

Cross cutting/horizontal issues: soft law and boards of appeal

Chapter VIII

European Union Soft Law by Agencies: an Analysis of the Legitimacy of their Procedural Frameworks

Penelope Rocca and Mariolina Eliantonio

TABLE OF CONTENTS: 1. Introduction. – 2. Definitions. – 3. Soft law of the agencies and the hypotheses. – 3.1. Different kinds of soft law issued by each agency. – 3.2. Research hypotheses. – 4. Analysis of the procedural frameworks for soft law issuance and evaluation of legitimacy. – 4.1. Assessment of different levels of proceduralisation. – 4.2. First group. – 4.3. Second group. – 4.4. Third group. – 4.5. Fourth group. – 4.6. Discussion. – 5. Conclusion.

1. Introduction

Over the last three decades, the European Union (EU) has seen an increase in the number of agencies that have been set up within its institutional framework and started what today is known as a process of «agencification». [1] At present, more than 40 agencies carry out diverse and very specific tasks, depending on the reason for their establishment. The rapid proliferation of these institutions can be explained by the belief of the political players in the European Union that agencies have a very important role in implementing the policies of the Union, [2] and allow these political players (in particular the Commission) to focus on other core tasks. [3] The agencies per-

[1] M. CHAMON, *EU Agencies: Does the Meroni Doctrine make sense?*, in *Maastricht J. Eur. Comp. L.*, Vol. 17, Issue 3, 2010, pp. 281-305.

[2] M. VAN RIJSBERGEN, *On the Enforceability of EU Agencies' Soft Law at the National Level: The Case of the European Securities and Markets Authority*, in *Utrecht L. Rev.*, Vol. 10, Issue 5, 2014, pp. 116-131.

[3] M. VAN RIJSBERGEN, *op. cit.*

form functions such as monitoring, gathering of information, drafting reports, providing technical advice, drafting recommendations, and they also have regulatory powers.[4] Not every agency is directly involved in the EU administrative framework; however, when they are, two main trends can be discerned: agencies can, among other things, engage in the adoption of binding instruments or issue soft law guidance.[5]

The legal basis for European Union agencies is not contained in the Treaties, nor is there any provision which explicitly governs the capacity of the Commission to delegate powers to them.[6] As a matter of fact, these institutions are created by secondary law (namely Regulations) and their powers are delineated by the case law of the European Court of Justice (CJEU). In particular, the *Meroni* judgement,[7] which was delivered in 1958, stated that EU actors can only delegate clearly defined executive powers to the agencies, to the exclusion of discretionary ones. This seems to imply that general regulatory powers cannot indeed be delegated.[8] However, as previously noted, more and more agencies are involved in the drafting of various kinds of soft law (such as recommendations, guidelines or opinions) which is general in nature. Since soft law is not formally binding and, thus, does not create any rights or obligations, it seems to escape the limitations established by the *Meroni* judgement. Yet, the importance of soft law must not be underestimated, as it may have considerable practical effects.[9] Indeed, the Court of Justice itself has underlined the relevance that soft law promulgated by agencies might have in interpreting the secondary law of the Union.[10] An important development that should be men-

---

[4] M. VAN RIJSBERGEN, *op. cit.*

[5] E. CHITI, *European Agencies' Rulemaking: Powers, Procedures and Assessment*, in *Eur. L.J.*, Vol. 19, Issue 1, 2013, pp. 93-110.

[6] A. FORGACS, *The Regulatory Powers of Agencies in the United States and the European Union*, in *Eur. Networks L. Reg. Q.*, Vol. 3, Issue 11, 2015, pp. 11-24.

[7] CJEU, 13 June 1958, Case 9/56, *Meroni & Co., Industrie Metallurgiche, S.A.S., v High Authority of the European Coal and Steel Community*, ECLI:EU:C:1958:7.

[8] T. VAN DEN BRINK-L. SENDEN, *Checks and Balances of Soft EU Rule-making*, study for the Directorate General for Internal Policies, policies department C: citizens' rights and constitutional affairs, 2012, PE 462.433.

[9] T. VAN DEN BRINK-L. SENDEN, *Checks and Balances of Soft EU Rule-making*, cit.

[10] See for example: CJEU, 10 september 2015, Case C-106/14, *Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage*

tioned is the recent *ESMA-short selling* case,[11] which brought a number of changes to the doctrine developed in *Meroni*. In this judgement the CJEU ruled that it is possible to delegate the power to adopt acts of general application to EU agencies if those acts are amenable to judicial review.[12] Yet, in *Belgium v Commission*[13] the Court made it clear that non-binding acts are hardly open to judicial review.

Because of the implications of the *ESMA-short selling* judgement, it is clear that there is a general lack of *ex post* control in regards to soft law measures issued by the European Union agencies, which, in turn, makes it essential to have at least some form of *ex ante* control. It is important to underline the fact that these two mechanisms operate in different ways and have unique functions which cannot be replaced by each other. However, the evident absence of the first shifts attention to the empirical need to test the second. This means that the procedure that leads to the adoption of soft law becomes an important factor in establishing the legitimacy of the soft law-making of the agencies.

There is extensive literature concerning the EU agencies, which covers their history, independence and legitimacy.[14] However, when discussing the independence of the agencies, the existing studies concentrate on the autonomy that these bodies have in relation to the EU institutions, the accountability of their actions and their possible abuse of power, all in relation to hard law measures issued by them. The literature about legitimacy is also limited to the hard law regulatory powers framework of the agencies. This leaves the substantial gap of establishing the legitimacy of the soft law-

et de l'aménagement de la maison (FMB) v Ministre de l'Écologie, du Développement durable et de l'Énergie, ECLI :EU:C:2015:576, para. 28.

[11] CJEU, 22 January 2014, Case 270/12, *United Kingdom of Great Britain and Northern Ireland v European Parliament and Council of the European Union* (*ESMA-short selling*), ECLI:EU:C:2014:18.

[12] CJEU, *ESMA-short selling*, cit., para. 53.

[13] GC, 27 October 2015, Case T-721/14, *Kingdom of Belgium v European Commission*, ECLI:EU:T:2015:829.

[14] See for example: R. DEHOUSSE, *Regulation by networks in the European Community: the role of European agencies*, in *J. Eur. Pub. Pol'y*, Vol. 4, Issue 2, 1997, pp. 246-261; A. WONKA-B. RITTBERGER, *Credibility, Complexity and Uncertainty: Explaining the Institutional Independence of 29 EU Agencies*, in *West Eur. Pol.*, Vol. 33, Issue 4, 2010, pp. 730-752. M. BUSUIOC-D. CURTIN-M. GROENLEER, *Agency growth between autonomy and accountability: the European Police Office as a 'living institution'*, in *J. Eur. Pub. Pol'y*, Vol. 18, Issue 6, 2011, pp. 848-867.

making of EU agencies. As mentioned, soft law is an extremely important tool often used by EU institutions and agencies, which frequently creates practical effects. However, in spite of its significance, research on soft law in relation to European Union agencies is lacking. Only very few authors, mostly Chiti, van den Brink and Senden and Korkea-aho (this last focusing on the ECHA),[15] have touched upon the procedural framework for the adoption of soft law by the agencies. In this regard, it is also worth mentioning the recent study published by Vos,[16] which presents an overview of all EU agencies, discussing various key points such as their legal basis, constitutionalisation, relationship with EU institutions and stakeholders, parliamentary scrutiny and delegation of powers. However, this document does not have a specific focus on soft law in particular. One final piece of research to be mentioned is that of Vaughan,[17] which focuses on 14 agencies, but mainly discusses the unclear nature of the guidance of the agencies, the forms and lengths of the documents and difficulties in accessing them because of poorly organised websites. This research, therefore, attempts to fill this gap by providing an analysis of the way in which the European Union agencies produce soft law, with a view to inferring the extent to which the process is legitimate. The research, therefore, aims at contributing to the existing literature on EU agencies by analysing, in the setting of soft law, the existence (or otherwise) of sufficient *ex ante* control mechanisms over the power of the agencies to issue soft law, given the lack of *ex post* checks.

Today, in practice, most EU agencies issue some kind of soft law; however, there are in particular 20 agencies[18] whose founding Regulation *ex-*

[15] See E. CHITI, *op. cit.*, T. VAN DEN BRINK-L. SENDEN, *op. cit.*, and E. KORKEA-AHO, *Laws in Progress? Reconceptualizing Accountability Strategies in the Era of Framework Norms*, in *Transnat'l Envtl. L.*, Vol. 2, Issue 2, 2013, pp. 363-385.

[16] E. VOS, *Eu Agencies, Common Approach and Parliamentary Scrutiny*, Study, European Parliamentary Research Service, 2018.

[17] S. VAUGHAN, *Differentiation and Dysfunction: An Exploration of Post-Legislative Guidance Practices in 14 EU Agencies*, in *Cambridge Y.B. Eur. L.Stud.*, Vol. 17, 2015, pp. 66-91.

[18] The agencies are: EUIPO (European Union Intellectual Property Office), CPVO (Community Plant Variety Office), ECHA (European Chemical Agency), EBA (European Banking Authority), EIOPA (European Insurance and Occupational Pensions Authority), ESMA (European Securities and Markets Authority), ESRB (European Systemic Risk Board), EMA (European Medicines Agency), EFSA (European Food and Safety Authority), EMSA (European Maritime Safety Agency), EASA (European Aviation Safety Agency),

plicitly gives them the power to issue soft law. The scope of this contribution will be limited to the study of those 20 agencies. The contribution will analyse the founding Regulations of the selected European agencies and their rules of procedures, where they exist. In order to evaluate their level of legitimacy, this contribution starts with an analysis of the degree of details and precision of the procedures that lead to the issuing of soft law by each agency. This is done by looking at three criteria, which are (i) access to documents, (ii) accountability and (iii) participation, and which constitute indicators of the 'proceduralisation' of soft law issuance for each agency. As will be explained in Section 2, legitimacy will be evaluated based on these three proceduralisation criteria on the premise that the higher the level of proceduralisation, the higher the level of legitimacy. Hence, a high, medium, or low degree of proceduralisation in the soft law-making powers of the agencies selected will correspond, respectively, to a high, medium, or low legitimacy of these powers.

The research will be divided into four main parts. In the next section *legitimacy* and *soft law* will be defined, in order to have one standard of evaluation for the procedures and one for the selection of the EU agencies which are the focus of this contribution. In Section 3, hypotheses will be formulated on the expected level of legitimacy of the agencies. This will be based on an analysis of the different kinds of soft law that each agency issues. Section 4 examines the levels of proceduralisation of each agency and, based on this, evaluates their legitimacy. To conclude, all the relevant findings will be summarised and suggestions for future research will be given.

2. Definitions

Before delving into the heart of the research, some important concepts need to be defined in order to reach the evaluative stage of this contribution and reach any conclusions.

ENISA (European Network and Information Security Agency), ECDC (European Centre for Disease Prevention and Control), ERA (European Railway Agency), ACER (Agency for the Cooperation of Energy Regulators), EUROFOUND (European Foundation for the Improvement of Living and Working Conditions), EMCDDA (European Monitoring Centre for Drugs and Drug Addiction), FRA (European Union Agency for Fundamental Rights), EDA (European Defence Agency), BEREC (Body of European Regulators of Electronic Communications).

First, the notion of *legitimacy* has to be determined. Schmitter broadly phrased the concept as «a shared expectation among actors in an arrangement of asymmetric power such that the actions of those who rule are accepted voluntarily by those who are ruled because the latter are convinced that the actions of the former conform to pre-established norms. Put simply, legitimacy converts power into authority and, thereby, establishes simultaneously an obligation to obey and a right to rule». [19]

Schmitter's definition, however, is only helpful for a broad delineation of the concept, and is mostly used to elucidate this notion in regard to hard law measures, as it would be incorrect to talk about «an obligation to obey» with regard to soft law. Most of the authors who have examined the concept of legitimacy in the context of the European Union make a more specific distinction between *input, output* and *throughput* legitimacy. [20] *Input* legitimacy refers to the political participation by the people, *output* legitimacy to the effectiveness of the policy results for the people, [21] and *throughput* legitimacy to the decision-making and procedural aspects and consists of the components of legality, quality and transparency. [22]

While legality is linked to the existence and effectiveness of the rule of law (and very rarely creates issues), the quality of decision-making rests on the assumption that when a process allows room for discussion, argument, mutual learning and reason-giving, the quality of the decision-making process is higher than in one consisting of mere bargaining. [23] The last aspect of *throughput* legitimacy, which is the focus of the analysis, is that of transparency. This concept refers primarily to the access to documents by citizens, accountability, participation and openness. [24] In other words, it means that a

---

[19] P.C. SCHMITTER, *What is there to legitimize in the European Union… and how might this be accomplished?*. Institute for Advanced Studies, Vienna, 2001.

[20] See for example: F.W. SCHARPF, *Governing in Europe: Effective and Democratic?*. Oxford, Oxford University Press, 1999 and M. ZÜRN, *Democratic Governance Beyond the Nation-State: The EU and Other International Institutions*, in *Eur. J. Int'l Rel.*, Vol. 6, Issue 2, 2000, pp. 183-221.

[21] V.A. SCHMIDT, *Democracy and Legitimacy in the European Union Revisited: Input, Output and 'Throughput*, in *Pol. Stud.*, Vol. 6, Issue 1, 2013, pp. 2-22.

[22] R. HOLZHACKER, *Democratic Legitimacy and the European Union*, in *J. Eur. Integration*, Vol. 29, Issue 3, 2007, pp. 257-269.

[23] T. RISSE-M. KLEINE, *Assessing the Legitimacy of the EU's Treaty Revision Methods*, in *J. Com. Mar. St.*, Vol. 45, Issue 1, 2007, pp. 69-80.

[24] A. ALEMANNO, *Unpacking the principle of openness in EU law: transparency, participation and democracy*, in *Eur. L. Rev.*, Vol. 39, Issue 1, 2014, pp. 72-90.

process is transparent if, during the decision-making process, it is possible to precisely determine who issues the final decision and is therefore accountable for it, who the stakeholders are who have to be consulted, involved in the discussion or drafting of the decision and that there is access of the final documents for the public. [25] The concept of openness has a very broad meaning, and the TFEU defines it as the promotion of good governance and participation of civil society, [26] which in substance encompasses the abovementioned components.

As previously mentioned, this research focuses on the procedural aspect of EU soft law-making by European Union agencies. For this reason, the criteria that will be used to evaluate the extent to which those procedures are legitimate are the ones ascribed to *throughput legitimacy* and specifically the criterion of transparency.

This means that, for the purposes of this contribution, there will be a high degree of throughput legitimacy when the soft law documents produced by an agency are accessible to the public in every language of the Union, when it is clear who is the body within the agency that is accountable for the final soft law measure (for example the management or administrative board or scientific expert groups), and when it is equally clear who the stakeholders are who have to be consulted in order to draft the soft law document. The degree of transparency will be lower if not all of the soft law documents are accessible to the public (or if, for example, individuals have to pay for them, register, or availability is limited to certain languages), when it is not entirely clear who is accountable for the final document, and which stakeholders have to be consulted. Consequently, there will be no transparency when there is no access to any soft law measure, it is impossible to know who is responsible for the final document, and who has to be consulted in the process.

The components of legality and quality will not be tested in the course of this research. The reason for excluding the element of legality is that there would be a high degree of this when there is a clear legal basis for the issuance of soft law by the EU agencies. Since the contribution focuses on the agencies that have the power to issue soft law which specifically stems from

---

[25] S. SMISMANS, *Regulating interest group participation in the European Union: changing paradigms between transparency and representation*, in *Eur. L. Rev.*, Vol. 39, Issue 4, 2014, pp. 470-492.

[26] Art. 15(1) TFEU.

their founding Regulation, it is already clear that there will always be a high degree of legality. Therefore, there is no need to further analyse it. The quality component, on the other hand, will be left out of the scope of this contribution because of the practical difficulty that its analysis implies. In fact, it would require an examination of the actual content of each soft law document issued and an evaluation of the extent to which their substance has followed the discussions and negotiations that led to its drafting and adoption. Given the type of analysis required, this criterion will not be tested. However it ought to be highlighted that there is certainly a need to conduct further research in this regard.

The second concept that must be defined is that of *soft law.* Numerous definitions have been given for it. Thürer states that it entails «commitments which are more than policy statements but less than law in its strict sense. They all have in common, without being binding as a matter of law, a certain proximity to the law or a certain legal relevance». [27] A second definition is provided by Snyder, namely «rules of conduct which, in principle, have no legally binding force but which nevertheless may have practical effects». [28] Another definition is given by Senden, who defines soft law as encompassing «rules of conduct which are laid down in instruments which have not been attributed legally binding force as such, but nevertheless may have certain (indirect) legal effects, and that are aimed at and may produce practical effects». [29] All of these interpretations have a similar focus, namely that the rule must prescribe a conduct or behaviour, it must not be legally binding and it may produce some practical effects. Given the affinity of the definitions, for the purpose of this contribution the standard used to select the EU agencies that issue soft law will be Senden's description. Therefore, the abovementioned agencies have been selected based on this definition of soft law.

---

[27] D. THÜRER, *The role of soft law in the actual process of European integration*, in O. JACOT-GUILLARMOD-P. PESCATORE (eds.), *L'avenir du libre-échange en Europe: vers un Espace économique européen?*, Polygraphischer Verlag, Zürich, 1990, p. 132.

[28] F. SNYDER, *The Effectiveness of European Community Law: Institutions, Processes, Tools and Techniques*, in *Mod. L. Rev.*, Vol. 53, Issue 1, 1993, pp. 19-54.

[29] L. SENDEN, *Soft Law in European Community Law. Its relationship with legislation.* Hart Publishing, Oxford, 2004, p. 104.

3. Soft law of the agencies and the hypotheses

3.1. Different kinds of soft law issued by each agency

As stated in the previous section, the agencies selected for this study issue soft law as defined by Senden. However, closer examination shows that they differ with respect to the *kind* of soft law that they issue. An analysis of the soft law measures issues by the selected EU agencies has made the identification of four types of soft law possible.

The first category comprises soft law measures which contain technical and specific guidelines which mostly explain requirements for compliance with specific EU laws. The EASA, ECHA, EFSA, EBA, EIOPA, ESMA, ESRB, BEREC, ACER and EMSA issue soft measures which are part of this group. For example, the EASA issues, *inter alia,* what it refers to as «acceptable means of compliance», which are, in fact, soft regulations which give guidance on how to implement, use, or interpret more specific hard law (such as the Guidance Material on air operations explaining Regulation 965/2012). On the same line of reasoning, the EMSA also issues Technical Recommendations to Member States on how to implement Directives.

Second, there are soft law measures which also come in the form of technical guidelines, but they mainly help explain the steps to be taken in order to make an application for an authorisation for a specific sector. Examples of this group are the soft law documents issued by the EMA, CPVO and EUIPO. For instance, the CPVO has a set of guidelines which indicate the steps for how to apply for plant variety protection, the EUIPO for trade mark and designs applications and the EMA for preparing marketing authorisations for human medicines.

The third group comprises soft law measures aimed at the dissemination of comprehensible and high-quality information. These soft law measures are issued by the EMCDDA, ECDC, FRA and EDA. A concrete example in this respect is the document containing the ECDC guidelines for the surveillance of native mosquitoes in Europe, or that on the EMCDDA guidelines on school-based interventions to prevent the uptake of smoking among children.

The last group is composed of soft law measures produced by the ERA, EUROFOUND and ENISA. These measures come in the form of technical documents mainly addressed to the Commission in order to help it develop further EU legislation. For example, the ERA and ENISA, *inter alia*, draft

recommendations on possible amendments to existing Regulations concerning, respectively, the railway and the information security sector. The EUROFOUND soft law is also addressed to the Commission, as it presents it with proposals and guidelines for improving the current hard law on, among other things, problems specific to certain categories of workers, and long-term aspects for improvement of the environment and distribution of human activities in time and space.

3.2. Research hypotheses

In the light of the different types of soft law that the agencies issue, it is possible to formulate certain hypotheses regarding the level of legitimacy that might be expected from each of them.

In general, it could be said that the agencies which issue soft law measures that are somewhat connected with hard EU law might be expected to have a high level of legitimacy. Indeed, these documents serve the purpose of ensuring that hard law is correctly understood and applied by individuals. If the soft law provisions are drafted in terms which are vague or unclear, this might lead to infringements of hard law, because the soft law usually clarifies or explains provisions of existing hard law. These infringements of hard law measures could therefore lead to concrete sanctions. Thus, the soft law of agencies that explains what the requirements are for compliance with EU law might be expected to have a high degree of legitimacy. However, the soft law of agencies which explains how to submit applications for an authorisation for a specific sector also clearly has a connection with hard law. In fact, the authorisation which triggers the applicability of other binding rules is usually issued only if the guidelines prescribed in the soft law measures are followed. This means that their legitimacy might also be expected to be high. Therefore, the first hypothesis of this study is that the soft law issued by the EASA, ECHA, EFSA, EBA, EIOPA, ESMA, ESRB, BEREC, ACER, EMSA, EMA, CPVO and EUIPO might be expected to have a high level of legitimacy.

The second hypothesis is that the soft law issued by the ERA, EUROFOUND and ENISA might be expected to have a medium level of legitimacy. Here the soft law instruments remain «internal» to the EU institution (because the measures are mainly addressed to the Commission), as they could serve as a basis for EU legislation. This means that the soft law also has a connection to hard law, but a less close one than that of the last group.

In fact, in practice the soft law does not always become the basis of further EU legislation and it is not directed primarily to citizens.

The final hypothesis holds that the soft law issued by the EMCDDA, ECDC, FRA and EDA might be expected to have a low level of legitimacy. This is because these agencies mainly disseminate high-quality information and are not involved with the issuance or compliance with hard law.

Table 1. – Hypotheses

Expected level of legitimacy	Soft law which explains existing hard law	Soft law which explains how to submit applications for a specific sector	Soft law addressed to the Commission and serving as basis for future hard law	Soft law which disseminates high-quality information
High	EASA, ECHA, EFSA, EBA, EIOPA, ESMA, ESRB, BEREC, ACER, EMSA	EMA, CPVO, EUIPO		
Medium			ERA, EUROFOUND, ENISA	
Low				EMCDDA, ECDC, FRA, EDA

4. Analysis of the procedural frameworks for soft law issuance and evaluation of legitimacy

4.1. Assessment of different levels of proceduralisation

The 20 agencies have been selected based on the fact that they have been granted what can be referred to as a *de jure* power to issue soft law. In this case, this definition means that, among all the EU agencies, those with founding Regulations which explicitly grant them the competence to issue soft law have been chosen. The decision rests on two main reasons. Firstly, those agencies are the ones that produce the most soft law documents if compared to the agencies that exercise a *de facto* power of issuing soft law measures. This means that, because of their very prolific activity, the question of legitimacy of their procedures poses itself even more powerfully. Secondly, the selection is narrow enough to allow an accurate and complete

analysis but, at the same time, it encompasses a sufficiently large and diverse number of agencies which increases the reliability of the study.

As mentioned in the introduction, in order to evaluate the legitimacy of the procedures for the adoption of soft law of the 20 agencies, an analysis of the procedures themselves, based on aspects relating to access to documents, accountability and participation has been carried out. This examination was based on an analysis of the founding Regulation of each agency selected and, where it exists, of their Rules of Procedure, which are internal documents drafted by the agencies themselves.

On this basis, it is possible to categorise the agencies into four groups, depending on their different levels of proceduralisation. There are agencies where the level of proceduralisation is high, since they have both detailed rules which prescribe public access to documents, and indicate who is accountable for the soft law documents issued by them, and they have separate rules of procedure which explain which stakeholders have to be consulted in the decision-making process leading to the issuance of soft law measures. On the contrary, some agencies display a low degree of proceduralisation, as they have rules about access to documents and accountability, but no rules of procedure which explain which stakeholders have to be involved in the issuing of soft law. In between those two extremes, two levels have been found, a medium-high and a medium-low one. These comprise agencies that also have provisions about access to documents and accountability, but which have only generic articles in their founding Regulation about consultations for soft law issuance accompanied by rules of procedure of the internal body which issues soft law (medium-high level). For the medium-low subgroup, there are merely articles in the Regulation which provide generic indications about the stakeholders to be involved in the decision-making process leading to the issuance of soft law measures.

Those findings are of particular importance as they clearly indicate that the main difference at the core of the grouping according to levels of proceduralisation (and, hence, also of legitimacy, as these two factors have been linked together from the beginning of the research) lies in particular in one of the three criteria used, namely participation. In fact, all of the agencies generally possess precise and detailed rules which cover access to documents and accountability aspects. Those rules are similar in all of the agencies. The same is not true for the participation requirement.

Table 2. – Levels of proceduralisation

LEVEL OF PROCEDURALISATION	ACCESS TO DOCUMENTS	PARTICIPATION	ACCOUNTABILITY
HIGH	Detailed rules which prescribe public access to documents	Separate rules of procedure for issuing soft law or on the stakeholders to be involved in the process	Precise rules which indicate the body accountable for the soft law documents
MEDIUM-HIGH	Detailed rules which prescribe public access to documents	Vague articles in the founding Regulation about consultations for issuing soft law and separate rules of procedure of the body of the agency which issues soft law	Precise rules which indicate the body accountable for the soft law documents
MEDIUM-LOW	Rules which prescribe public access to documents	Vague articles in the founding Regulation about the stakeholders to be involved in the consultations for issuing soft law	Precise rules which indicate the body accountable for the soft law documents
LOW	Rules which prescribe public access to documents	No rules on participation for the process of issuing soft law	Precise rules which indicate the body accountable for the soft law document

The following subsections specifically analyse the proceduralisation and legitimacy of each agency, placing them in their corresponding group based on the table above.

4.2. First group

The first group comprises the agencies that have a high level of proceduralisation. Those are the EASA, EMA, ECHA, EBA, EIOPA and ESMA.

With regard to the access to documents they all contain articles in their founding Regulation stating that Regulation 1049/2001 shall apply.[30] This Regulation essentially provides that citizens of the European Union shall

[30] Regulation (EC) 216/2008, 20 February 2008, [2008] OJ L 79/1, Art. 58. Regulation (EC) 726/2004, 31 March 2004, [2004] OJ L 136/1, Art.73. Regulation (EC) 1907/2006, 18 December 2006, [2006] OJ L 396/1, Art. 118. Regulation (EC) 1093/2010, 24 November 2010, [2010] OJ L 331/12, Art. 72. Regulation (EC) 1094/2010, 24 November 2010, [2010] OJ L 331/48, Art. 72. Regulation (EC) 1095/2010, 24 November 2010, [2010] OJ L 331/84, Art. 72.

have a right of access to documents of the institution, with «documents» being defined as any content (regardless of the medium of its expression) which falls within the sphere of responsibility of the institution.[31] More specifically, the EASA also has an explicit obligation to publish in all the official languages of the Union the recommendations that it issues to the Commission.[32] The EBA, EIOPA and ESMA have, in their rules of procedure, provisions stating that there should be public access to documents produced by the stakeholders groups involved in the decision-making process of soft law.[33] However, in practice, the soft law documents (which are nonetheless available on the official website of the agencies) are accessible only in English. This holds true for the EBA and ECHA as well, the websites of which are available in 23 out of the 24 official languages of the EU.

The EASA, EMA and ECHA furthermore have separate documents which specifically lay down detailed provisions concerning the creation of soft law. Indeed, the management board of the EASA has published a decision which contains provisions about the adoption of opinions, certification specifications, acceptable means of compliance and guidance material.[34] This document consists of precise information about how to commence the process of rule-making, the drafting of rules, consultations, review of comments, adoption, publication, ex post evaluation and access to those documents. The EMA, similarly, has also adopted a procedure for guidelines and related documents[35] which explains the legal status and the different types of guidelines of EMA, and a detailed ten-step process to be followed in drafting. The process includes rules about the development of the draft measure, the adoption and release for consultation, the preparation of the fi-

---

[31] Regulation (EC) 1049/2001, 30 May 2001, [2001] OJ L 145/43, Art. 2(1) and 3(a).

[32] Regulation (EC) 216/2008 (n 27), Art. 32(1)(b).

[33] EBA, *Rules of Procedure of the Banking Stakeholder Group*, 26 October 2015, EBA BSG 2015 067, Art. 16. EIOPA, *Insurance and Reinsurance Stakeholder Group and Occupational Pensions Stakeholder Group Rules of Procedure*, April 2016, EIOPA-16/383, Art. 15. ESMA, *Decision of the Securities and Markets Stakeholder Group Rules of Procedure*, 29 January 2014, ESMA/2014/SMSG/002, Art. 18.

[34] EASA Management Board, *Decision n 18-2015 replacing Decision 01/2012 concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications, acceptable means of compliance and guidance material ('Rulemaking Procedure')*, 15 December 2015.

[35] EMA, *Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework*, 18 March 2009, EMEA/P/24143/2004 Rev. 1 corr.

nal version and the implementation phase. The ECHA also adopted a document containing a consultation procedure for guidance documents.[36] It contains detailed rules on the commencement of the consultation procedure, the ECHA partners, and the precise steps to be taken for issuing guidance. In all three documents, it is clear who the stakeholders involved in the process of producing the relevant soft law documents are, since the procedural steps are laid down in a detailed way and it is possible to discern the different actors involved during the different phases.

The EBA, EIOPA and ESMA all have in their founding Regulation an article which states that, for the adoption of recommendations, «open public consultations» shall be held where appropriate with the interested stakeholders.[37] In this regard, each of the agencies have further precise and detailed rules of procedure for the respective stakeholder groups. They lay down rules about, *inter alia*, membership, meetings, agenda setting, consultation, decision-making, minutes and transparency.[38] The interesting aspect is that a detailed description of the composition of those groups is found in the respective Regulations.[39] The description, although very detailed as it lists the number and the exact sector from which each member must come, does nevertheless not provide a precise insight into the exact stages in which those actors have to be consulted.

Regarding this last aspect, accountability, all of the agencies have articles which empower either the board of supervisors[40] or the management board[41] to adopt soft law instruments and, therefore, renders these bodies accountable for the soft law issued.

In summary, all these agencies have precise provisions concerning access

---

[36] ECHA Management Board, *Second revision to the Consultation Procedure for Guidance*, 18 December 2013, MB/63/2013 (final).

[37] Regulation (EC) 1093/2010 (n 27), Art. 16(2). Regulation (EC) 1094/2010 (n 27), Art. 16(2). Regulation (EC) 1095/2010 (n 27), Art. 16(2).

[38] EBA, *Rules of Procedure of the Banking Stakeholder Group* (n 30). EIOPA, *Insurance and Reinsurance Stakeholder Group and Occupational Pensions Stakeholder Group Rules of Procedure* (n 30). ESMA, *Decision of the Securities and Markets Stakeholder Group Rules of Procedure* (n 30).

[39] Regulation (EC) 1093/2010 (n 27), Art. 37(2). Regulation (EC) 1094/2010 (n 27), Art. 37(2). Regulation (EC) 1095/2010 (n 27), Art. 37(2).

[40] Regulation (EC) 1093/2010, art. 43.

[41] Regulation (EC) 216/2008 (n 27), Art. 33. Regulation (EC) 726/2004 (n 27), Art. 66. Regulation (EC) 1907/2006 (n 27), Art. 78.

to documents and accountability, and the rules about participation are also generally detailed. Therefore, it can be concluded that, for the purpose of this contribution, their level of proceduralisation is high.

After having analysed the proceduralisation for soft law adoption, it is now possible to evaluate the level of transparency (and therefore legitimacy) of the agencies that are part of this group. The access to documents aspect is present to a medium degree, as the fact that the soft law measures are available only in English is a consistent limitation. However, accountability and participation are characterised by a high level of transparency. This also holds true for the EBA, EIOPA and ESMA. The fact that there are no explicit rules which more clearly lay down each and every step that leads to the adoption of the instrument in question renders their rules on participation slightly less developed than those of the EASA, EMA and ECHA. Nevertheless, the amount of information given allows the public to know the actors which contribute to the adoption of soft law, their selection and working procedures. This means that these agencies also have a high degree of participation. This conclusion is also in line with Vaughan's findings,[42] where, in his paper, he states that these three agencies have a quite detailed way of drafting obligations in relation to the guidance that they provide. Therefore, it can be concluded that the overall level of legitimacy of the procedures to issue soft law of the agencies in this category is high.

Table 3. – High level of proceduralisation and legitimacy

AGENCIES	ACCESS TO DOCUMENTS	PARTICIPATION	ACCOUNTABILITY
EASA, EMA, ECHA	Regulation 1049/2001 applies	Separate detailed rules of procedure on how to adopt soft law (including the stakeholders to be consulted)	Management board
EBA, EIOPA, ESMA	Regulation 1049/2001 applies	Separate rules of procedures on the stakeholder groups that must be consulted when issuing soft law	Board of supervisors

[42] See S. VAUGHAN, *op. cit.*

4.3. Second group

The second group consists of agencies which have a lower level of proceduralisation if compared with the first. Part of this category are the BEREC, ESRB, CPVO, FRA, ACER and ERA.

Apart from the ESRB, the rules of procedure of which nonetheless prescribe the publication of all the documents of the agencies approved by the General Board in all the EU languages,[43] all the other agencies state that Regulation 1049/2001 is, again, applicable.[44] The official websites of the ESRB, FRA and ACER are available in the 24 official languages of the EU. However, in practice the soft law documents of the agencies that are part of this group are available mostly in English only.

With regards to participation, the common pattern here shows that there is generally a vague article in the founding Regulation which provides that consultations with interested parties shall be held, accompanied by rules of procedure of the body within the agency that specifically issues soft law. However, apart from the composition of the relevant body of the agency, it is unclear precisely which stakeholders are to be involved in the decision-making process and it is just as unclear at what stage the stakeholders have to be consulted. In other cases, there are articles in the Regulation which indicate quite precisely who the stakeholders are who have to be consulted for the drafting of the soft law instrument. However, apart from the designation of who needs to be consulted, there is no information about their exact role and rules of procedure (and, therefore, at what stage they need to be consulted). The BEREC, for example, states in its founding Regulation that it «may, where appropriate, consult the relevant national competition authorities before issuing its opinion to the Commission»[45] and that consultations with interested parties shall be held before issuing soft law.[46] Moreover, it states that the Board of Regulators, whose composition is laid down in Article 4(2), shall issue soft law.[47] In this respect, there are precise rules of pro-

[43] ESRB, *Rules of Procedure of the European Systemic Risk Board*, 20 January 2011, ESRB/2011/1, Art. 27(1).

[44] Regulation (EC) 1211/2009, 25 November 2009, [2009] OJ L 337/1, Art. 22. Regulation (EC) 168/2007, 15 February 2007, [2007] OJ L 53/1, Art. 17. Regulation (EC) 2100/94, 27 July 1994, [1994] OJ L 227/1, Art. 33a. Regulation (EC) 713/2009, 13 July 2009, [2009] OJ L 211/1, Art. 30. Regulation (EC) 881/2004, 29 April 2004, [2004] OJ L 164/1, Art. 37.

[45] Regulation (EC) 1211/2009 (n 40), Art. 3(3).

[46] Regulation (EC) 1211/2009, Art. 17.

[47] Regulation (EC) 1211/2009, Art. 5(1).

cedure of the Board of Regulators which, however, cannot be accessed unless a person is registered on the official page.[48] In any case, there are no other indications about the nature and role of these interested parties. The ESRB is a little more precise as, in its rules of procedure, it indicates specifically the entities from which it can seek advice before drafting guidelines.[49] Yet, again, there is no information about their role in the decision-making process. The same could be said for the ACER and the ERA. For example, the founding Regulation of ACER specifically indicates that, in particular before drafting guidelines, the agency «shall consult extensively and at an early stage with market participants, transmission system operators, consumers, end-users and, where relevant, competition authorities».[50] However, differently from the other agencies in this group, the ACER and ERA do not have any separate relevant rules of procedure nor do they indicate more precisely at what stage the stakeholders have to be consulted.

With regards to accountability, all the agencies refer to one of their internal bodies as the one adopting the opinions or recommendations, which is therefore the organ accountable for them.[51]

Therefore, the agencies in this category are characterised by a medium-high level of proceduralisation. Despite the fact they all have rules on public access to documents and accountability, they are much more vague in relation to the stakeholders to be involved in the decision-making process. There usually is a generic article in the Regulation accompanied by the rules of procedure of the body within the agency which issues soft law, or a more precise one which indicates the stakeholders to be consulted, but not a detailed description of their involvement.

Based on the above, it can be concluded that the level of legitimacy of these agencies is also medium-high. This is because the access to document element of transparency is present to a medium degree, as the soft law documents are accessible solely in English. On the other hand, there is fully fledged accountability. Regarding participation, its level is lower than the

---

[48] See: https://www.acer.europa.eu/en/The_agency/Organisation/Board_of_Regulators/Pages/Rules-of-procedure.aspx, last accessed 11 July 2018.

[49] ESRB, *Rules of Procedure of the European Systemic Risk Board* (n 39), Art. 18.

[50] Regulation (EC) 713/2009 (n 40), Art. 10.

[51] Regulation (EC) 1211/2009 (n 40), Art. 5. Regulation (EC) 1092/2010, 24 November 2010, [2010] OJ L 331/1, Art. 4(2). Regulation (EC) 2100/94 (n 40), Art. 36. Regulation (EC) 168/2007 (n 40), Art. 12. Regulation (EC) 713/2009 (n 40), Art. 15. Regulation (EC) 881/2004 (n 40), Art. 25.

first group, but it is nevertheless possible to have quite a considerable insight into it, as explained above.

Table 4. – Medium-high level of proceduralisation and legitimacy

AGENCIES	ACCESS TO DOCUMENTS	PARTICIPATION	ACCOUNTABILITY
BEREC, ESRB, CPVO, FRA	Regulation 1049/2001 applies	Vague articles in the Regulation stating that consultations with interested parties must be held and separate rules of procedure of the body of the agency which issues soft law	BEREC: Board of Regulators ESRB: General Board CPVO: Administrative Council FRA: Management Board
ACER, ERA	Regulation 1049/2001 applies	Precise articles in the Regulation which clearly define the parties to be consulted for issuing soft law	ACER: Board of Regulators ERA: Administrative Board

4.4. Third group

The third group comprises agencies that have a lower level of proceduralisation than the second. These agencies lack any specific set of rules of procedure for the adoption of soft law and the rules on participation are vague. The EMCDDA and EFSA are part of this category.

With regard to access to documents, the EMCDDA states that the rules of Regulation 1049/2001 shall apply, [52] while the EFSA is more vague, affirming that «the Authority shall ensure wide access to the documents which it possesses». [53] It is worth noting that the official website of the EFSA is present in four languages of the European Union, namely English, Italian, German and French. However, the actual documents containing the guidelines are available only in English. The soft law documents of the EMCDDA are also available only in English.

Regarding participation, the rules of the agencies are not clearly defined. Article 9 of the Regulation of EFSA, for instance, prescribes open and transparent public consultations, but it does not mention whether they must

[52] Regulation (EC) 1920/2006, 12 December 2006, [2006] OJ L 376/1, Art. 7.

[53] Regulation (EC) 178/2002, 28 January 2002, [2002] OJ L 31/1, Art. 41.

be held also for soft law issuance nor who should be the addressees of these public consultations. The EMCDDA follows more or less the same line with its Article 13(2). It states that the Scientific Committees, before delivering an opinion, shall take into consideration opinions expressed by national experts, with no further elaboration.

In terms of the accountability aspect, the management board and the executive director are accountable for the soft law documents of, respectively, the EMCDDA and the EFSA. [54]

Therefore, given the vagueness of the articles contained in the Regulations regarding stakeholders' involvement in consultations, these agencies are deemed to have a medium-low level of proceduralisation.

For the assessment of legitimacy, in spite of the relatively high degrees of the elements of access to documents and accountability, it can also be concluded that the procedure for the adoption of soft law of these two agencies is characterised by rather little transparency (medium-low level), as there is virtually no insight into the participation aspect.

Table 5. – Medium-low level of proceduralisation and legitimacy

AGENCIES	ACCESS TO DOCUMENTS	PARTICIPATION	ACCOUNTABILITY
EMCDDA, EFSA	EMCDDA: Regulation 1049/2001 applies EFSA: wide access to documents	EMCDDA: opinions of national experts must be taken into account EFSA: open and transparent public consultations shall be held (no specific reference to soft law-making)	EMCDDA: Management Board EFSA: Executive Director

4.5. Fourth group

The fourth and last group comprises the ENISA, ECDC, EMSA, EUROFOUND, EDA and EUIPO. Those agencies are characterised by a low level of proceduralisation for soft law-making.

For the access to documents aspect, they all make reference to Regulation 1049/2001. [55] The ENISA official website is available in four languages of

[54] Regulation (EC) 1920/2006 (n 48), Art. 9. Regulation (EC) 178/2002 (n 49), Art. 26.

[55] Regulation (EC) 526/2013, 21 May 2013, [2013] OJ L 165/41, Art. 18. Regulation

the EU, namely English, French, German and Greek. The websites of the EUROFOUND and EUIPO are available, respectively, in 28 languages (including 4 which are not official languages of the European Union) and 23 official ones. However, for the first two agencies the soft law documents are only accessible in English, while for the EUIPO the guidelines are available in English, French, German, Italian and Spanish. The EUIPO website also states that guidelines which entered into force before 2014 are accessible in all the languages of the EU, and that by the end of 2018 all of them are to be made available in all the EU languages.[56]

Regarding participation, their proceduralisation is almost inexistent. In fact, none of the founding Regulations of the agencies refer to consultations with stakeholders or procedures to be followed for the adoption of guidelines. In the same way they lack separate rules for the adoption of soft law. Agencies such as the ECDC, ENISA and EMSA merely give general indications of commitment to the principle of transparency in relation to the procedures of the agency and open access to documents.[57]

In terms of accountability, on the other hand, they refer to the management board,[58] governing board,[59] head of the agency,[60] administrative board[61] or the president of the office.[62]

In spite of the existence of rules on access to documents and accountability, these agencies are considered to have a low level of proceduralisation. They do not have any rule (generic or specific) which indicates any of the steps of the procedure to be followed for the adoption of soft law.

In the light of this analysis, it can be said that, generally, the access to documents aspect of legitimacy is present to a medium degree (even if it is

---

(EC) 851/2004, 21 April 2004, [2004] OJ L 142/1, Art. 20. Regulation (EC) 1406/2002, 14 June 2002, [2002] OJ L 208/1, Art. 4. Regulation (EC) 1365/75, 26 May 1975, [1975] OJ L 139/1, Art. 18a. Regulation (EC) 2015/1835, 12 October 2015, [2015] OJ L 266/55, Art. 30. Regulation (EC) 2017/1001, 14 June 2017, [2017] OJ L 154/1, Art. 149.

[56] See: https://euipo.europa.eu/ohimportal/en/trade-mark-guidelines, last accessed 11 July 2018.

[57] Regulation (EC) 1406/2002 (n 51), preamble 9 and Art. 4. Regulation (EC) 851/2004 (n 51), preamble 14 and 19 and Art. 20. Regulation (EC) 526/2013 (n 51), preamble 18 and Art. 16 and 18.

[58] Regulation (EC) 526/2013 (n 51), Art. 5. Regulation (EC) 851/2004 (n 51), Art. 14.

[59] Regulation (EC) 1365/75 (n 51), Art. 7.

[60] Regulation (EC) 2015/1835 (n 51), Art. 7.

[61] Regulation (EC) 1406/2002 (n 51), Art. 10.

[62] Regulation (EC) 207/2009, 26 February 2009, [2009] OJ L 78/1, Art. 89.

higher for the EUIPO), while accountability is present to the highest degree. However, there is an extremely low degree of participation. Therefore, it can be concluded that these agencies have an overall low level of legitimacy.

Table 6. – Low level of proceduralisation and legitimacy

AGENCIES	ACCESS TO DOCUMENTS	PARTICIPATION	ACCOUNTABILITY
EUROFOUND, EDA, EUIPO	Regulation 1049/2001 applies	No separate rules of procedure for adoption of soft law nor articles in the Regulation about consultations	EUROFOUND: Governing Board EDA: Head of the Agency EUIPO: President of the Office
ECDC, ENISA, EMSA	Regulation 1049/2001 applies	General articles in the Regulation about the transparency of the agencies' procedures	ENISA and ECDC: Management Board EMSA: Administrative Board

4.6. Discussion

From the above subdivision and analysis, it is possible to provide an overview of the level of proceduralisation and legitimacy of the process of soft law-making of the selected EU agencies.

The first and last categories are the ones which diverge the most. In fact, for the purpose of this study, the former group is characterised by a high level of legitimacy. On the other hand, the latter has a low level of legitimacy. Regarding the two remaining groups, which have been placed between the two extremes, it could be said that they are nonetheless closer to the category with the lowest level of proceduralisation and legitimacy. This is because, apart from the access to documents and accountability aspects, they provide little information about participation. They have no rules about the procedure to be followed for adopting soft law and they merely refer, more or less precisely, to consultations to be held with national authorities or stakeholders.

In the light of the findings, it is now possible to look at whether the hypotheses proposed above have been confirmed or refuted. It is clear that none of the three hypotheses have been fully confirmed.

It was expected that the EASA, ECHA, EFSA, EBA, EIOPA, ESMA, ESRB, BEREC, ACER, EMSA, EMA, CPVO and EUIPO would have high levels of legitimacy. However, only the EASA, ECHA, EBA, EIOPA, ES-

MA and EMA confirm this hypothesis. The BEREC, ESRB, ACER and CPVO are part of the category with a medium-high level of legitimacy. In this case, it could be argued that expectations have not been met by a small margin of error, since the latter agencies still fit into the second highest category. However, as is clear from the above analysis, there is a considerable 'procedural gap' between the first and the other three categories. In fact, the two middle groups are closer to the lowest one in terms of their level of proceduralisation and legitimacy. Moreover, the EUIPO and EMSA find themselves in the category with low legitimacy, and the EFSA in the one with a medium-low level. This clearly confutes the first hypothesis.

The second hypothesis held that the ERA, EUROFOUND and ENISA were expected to have a medium level of legitimacy in their procedures to issue soft law. This hypothesis has also not been fully confirmed. First, it is worth noting that, in the end, two medium categories have been found. The ERA is part of the group of agencies which have a medium-high level of legitimacy, which could be seen as a confirmation of the expectation related to it. However, both the ENISA and EUROFOUND have a low level of legitimacy. This refutes clearly the second hypothesis.

Last, the third hypothesis expected the EMCDDA, ECDC, FRA and EDA to have low levels of legitimacy. This has also been just partially confirmed. In fact, the ECDC and EDA are part of the last category, with low levels of legitimacy, which validates the hypothesis. However, the FRA and EMCDDA have medium levels. In particular, the former has a medium-high while the latter a medium-low level of legitimacy of the procedures to issue soft law.

Table 7. – Actual findings

Actual level of legitimacy	Soft law which explains existing hard law	Soft law which explains how to submit applications for a specific sector	Soft law addressed to the Commission and serving as basis for future hard law	Soft law which disseminates high-quality information
High	EASA, ECHA, EBA, EIOPA, ESMA	EMA		
Medium-high	BEREC, ESRB, ACER	CPVO	ERA	FRA
Medium-low	EFSA			EMCDDA
Low	EMSA	EUIPO	ENISA, EUROFOUND	ECDC, EDA

The general observation that can be made by looking at these results is that there seems to be no apparent logical pattern for the degree of legitimacy of the procedures to issue soft law of the selected 20 agencies. In fact, even though part of the hypotheses has been confirmed, it seems rather to be a confirmation by chance. In relation to the first hypothesis, out of 13 agencies only six fitted in the expected category. The rest were part of the remaining groups (four were in the category with medium-high legitimacy, one medium-low and two low). The second hypothesis has been confirmed by only one out of three agencies. The third by two out of four.

It is clear that, out of the three criteria used for the classification, the one of participation is particularly important. In fact, the access to documents and accountability aspects are present, in each group, roughly to the same extent, while the procedures explaining the participation of different stakeholders in the process of soft law creation differ consistently from group to group. This procedural difference, as just mentioned, does not seem to be dictated by the different kinds of soft law that each agency drafts. It is worth noting that the subdivision is not even governed by a temporal criterion. In fact, it could perhaps be expected that the agencies that are part of the first group were the most recently founded (in order to explain an improvement to recent criticism about legitimacy concerns). However, this is not the case. The EBA, EIOPA and ESMA were founded in 2011 and the ECHA in 2007, but the EASA was instituted in 2003 and the EMA as early as 1995. This considerable difference between the years of foundation of the agencies is present in all the four subgroups under examination. It might perhaps be interesting in future research to assess whether this subdivision can be explained by the different degrees (if they exist) of institutional accountability of the agencies, meaning their accountability before representing institutions (such as the Council and the European Parliament). This examination would have to be based on an analysis of the different accountability stages, such as the verification of whether an agency has an obligation to justify its conduct, whether it has to report it to other institutions, and the rectification stage, where the agency has to face the consequences of its conduct.

The findings of this contribution have serious implications. It has been shown how most of the agencies (14 out of 20) possess quite a low level of legitimacy for their procedure to issue soft law. It could therefore be said that only the six agencies of the first group have a level of legitimacy which is high enough to serve the purpose of being an effective *ex ante* control over their power to issue soft law. This means that the majority of agencies lacks effective *ex ante* and *ex post* controls. As mentioned in the introduc-

tion, soft law is an important tool which involves significant practical effects. It is because of these effects that legitimate and, in particular, transparent procedures are needed. Individuals are entitled to know how and by whom these documents are produced, in order to be able to exercise a form of control over possibly arbitrary decisions, fostering legal certainty and democratic beliefs. This research therefore provides tangible proof of a need to implement more transparent and legitimate procedures for the adoption of soft law by European Union agencies.

5. Conclusion

Because of their number and increasing scope of activities, EU agencies have become more and more important in the system of EU administrative governance. Their powers and responsibilities, however, are not clearly regulated in the Treaties of the Union, and are only enshrined in secondary law. When referring to soft law, in particular, the issue of conferral of powers and *ex post* control over the tasks of the agencies show how these powers are essentially unregulated. Hence the importance of discovering whether some form of *ex ante* control exists over the power to issue soft law by the agencies. Based on the foregoing, this research analysed the procedural framework of 20 selected agencies in order to infer how legitimate the process is.

Three hypotheses were created based on the level of legitimacy that might have been expected from each agency. In order to do so, the soft law issued by each agency has been analysed. The agencies where soft law has a strong link with EU hard law were predicted to have a high level of legitimacy, while the ones which merely disseminate high-quality information were expected to have a low one. In between there were agencies whose link with hard law is weaker than the first group, but nonetheless present.

None of these three hypotheses has been fully confirmed. It has been found that the agencies can be grouped into four different categories based on the different level of proceduralisation for the issuance of soft law and, consequently, also of legitimacy. In fact, these two factors have been linked together from the beginning of the research by using the same criteria of evaluation for both (namely access to documents, participation and accountability).

Only six agencies have a high level of legitimacy, while according to the hypotheses there should have been 13. The ones that come into this category, the EASA, EMA, ECHA, EBA, EIOPA and ESMA, display fully fledged participation. These agencies either have separate precise rules of procedure

expressly created for the adoption of soft law, or they have rules of procedures for the stakeholders groups to be consulted. In general, the access to documents aspect is present to a medium degree in relation to each of the four groups and accountability to the highest degree. Therefore, the element of participation played a particularly important role in the analysis.

The three other categories display a medium-high, medium-low and low degree of transparency (and therefore legitimacy). The BEREC, ESRB, ACER, CPVO, ERA and FRA are part of the second group, with a medium-high level of transparency. These agencies are characterised by either precise articles in the founding Regulation defining the stakeholders to be consulted, or more vague articles about consultation, accompanied by rules of procedure of the internal body of the agency empowered to issue soft law measures. Part of the third group, with a medium-low level of legitimacy, are the EFSA and EMCDDA. Their rules on participation do not display precise information, but merely refer to open and public consultations or consultations with national experts. Last, the ENISA, ECDC, EMSA, EUROFOUND, EDA and EUIPO are part of the fourth group, with a low level of legitimacy, as they only mention commitments to the principle of transparency with no further elaboration.

In spite of the categorisation, it can be said that the procedural gap between the last three groups and the first one is substantial. This means that the agencies of the first group can be said to be the only ones whose level of transparency is adequate in order to provide an actual control mechanism over the power of the agencies to issue soft law.

Therefore, the research showed how, as of today, the procedural framework of the majority of the 20 selected agencies provides for little transparency. Furthermore, it has been shown that four different levels of legitimacy can be identified, meaning that the selected agencies display some quite significant differences with regard to this aspect. However, their categorisation in terms of proceduralisation does not appear to be dictated by any logical pattern. Instead, the fact that all three hypotheses have been refuted shows that there is no discernible link between the transparency of the procedures to issue soft law, and the kind of soft law issued by the selected EU agencies. It can thus be concluded that there is a general need to enhance transparency and legitimacy in the process of soft law creation by the European Union agencies. Based on the foregoing, it could be beneficial to have a more homogeneous and streamlined framework for all the processes of soft law-making of the agencies. Such a solution could clearly enhance legal certainty, which is fundamental in terms of predictability of the actions of those

subjected to the (soft) law, and more democratic procedures. In this regard, a perhaps relevant source of inspiration for the improvement of transparency could be the ReNEUAL Model Rules on EU Administrative Procedure.[63] Those rules are draft proposals for legislation which take into consideration and try to reinforce general principles of EU law, among which we find transparency and legal certainty.[64] They have been drafted in relation to hard European law; however, it might be interesting to see whether they could also be applied regarding procedures for soft law-making or, if not, to try to draw on them. The Model Rules seem, indeed, to set precise standards regarding, *inter alia,* the procedures through which to achieve a greater involvement of citizens and enterprises in order to deepen the culture of participation, and to promote the duties of providing reasons and disclosure.[65] The application of those rules could undoubtedly benefit the transparency deficit of the agencies that are part of the second, third and fourth group, but could also be of use, if applied to all the agencies, for harmonisation purposes.

The present research focused on 20 agencies, being the ones that have been granted a *de jure* power to issue soft law. This is a limit of this contribution, as there are in total more than 40 agencies in the EU. This means that, in order to complete the picture, further research is needed to find out how legitimate the procedural framework for soft law creation is in relation to the agencies that have a *de facto* competence to promulgate soft law. Moreover, this contribution concentrated on the transparency aspect of legitimacy, leaving aside the component of legality and quality. Further research is therefore needed in order to test the quality component in relation to the present 20 agencies and to those issuing *de facto* soft law. One last *caveat* regards the theoretical approach of this contribution. This research has been carried out by looking at secondary and, mainly, primary sources in relation to the different agencies. However, these results should be subsequently tested empirically,[66] in order to find out *in concreto* how difficult it is to get information about soft law-making from each agency.

---

[63] P. CRAIG-H.C.H. HOFMANN-J. SCHNEIDER-J. ZILLER (eds.), *ReNEUAL Model Rules on EU Administrative Procedure*, Oxford University Press, Oxford, 2014.

[64] P. CRAIG-H.C.H. HOFMANN-J. SCHNEIDER-J. ZILLER (eds.), *ReNEUAL Model Rules on EU Administrative Procedure*, Book II- Administrative Rule-Making.

[65] P. CRAIG-H.C.H. HOFMANN-J. SCHNEIDER-J. ZILLER (eds.), *ReNEUAL Model Rules on EU Administrative Procedure*, Art. II-4 and II-5.

[66] The only empirical test concluded so far had been carried out by Korkea-aho in relation to the ECHA. See E. KORKEA-AHO, *op. cit*.