

EUROPEAN UNION RULES GOVERNING ADMINISTRATIVE PROCEDURES

*Laura Muzi**

Abstract

Within EU legislation could be found several rules concerning administrative decision-making which have been drawn, during the decades, from the principles elaborated by the EU courts and now enshrined in Art. 41 CFEU. Currently, those affected by a final decision of the administration can only rely on these principles and on sector specific legislation, to have their rights to an administrative due process granted. The attempts to create a specific code on EU administrative procedure have failed, due to the hesitancy of the Commission. This article tries to comprehend, through both a quantitative and a qualitative analysis, to what extent sector specific legislation considers procedural requirements and how the global picture would be affected by a piece of legislation providing for some general rules concerning EU administrative procedure. The assumption laying in the background is that such kind of code would not only affect the backsides of judicial activism but would also benefit the EU administration both in terms of transparency and legitimacy.

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* Post-doc fellow, University of Rome “Tor Vergata”

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1. An inquiry into administrative procedures according to sector-specific legislation

This paper illustrates the results of an inquiry into EU sector-specific legislation where the EU rule-makers addressed administrative procedural issues relating to a subject matter falling within the legislative competences of the European Union. It aims to provide an insight into EU legislation from the point of view of procedures, and thus to show how general principles on administrative procedure have been codified so far¹. The study is based on a quantitative analysis of EU legislation that includes norms concerning administrative procedure in whatever form they are drawn up by the legislator. Its scope is broad, too, given that it encompasses direct, composite and indirect administrative procedures².

¹ Since the mid-'90s, scholars have shed light on the lack in the European Union of an Administrative Procedure Act, the provisions concerning administrative procedure being scattered throughout sector-specific secondary legislation. K. Lenaerts-J. Vanhamme, *Procedural Rights of Private Parties in the Community Administrative Process*, in 34 *Common Mkt. L. Rev.* 531 (1997).

² S. Cassese, *Il diritto amministrativo europeo presenta caratteri originali?*, 53 *Riv. Trim. Dir. Pubbl.* 35 (2003); S. Cassese, *European Administrative Proceedings*, in 68 *Law & Contemp. Probs.* 21 (2004); G. della Cananea, *The European Union's Mixed Administrative Proceedings*, in 68 *Law. & Contemp. Probs.* 197 (2004); H. Hofmann, *Composite Decision Making Procedures in EU Administrative Law*, in H. Hofmann, A. Türk (eds.), *Legal Challenges in EU administrative Law: Towards an*

From a methodological point of view, the backbone of the analysis consisted therefore in the collection of data through the official EU search engine EUR-lex³, questioned with different keywords. The purpose was to have an insight into how the principle of, and the right to good administration have been declined in secondary, sector-specific legislation over the years, bearing in mind that this process of rule-making is the adaptation of the work of EU judges in decades of case-settlements during which principles of administrative procedure were progressively outlined⁴.

As a starting point have been considered the three main features of good administration as they now are encompassed in Article 41 of the CFR⁵, since this provision represents – thus far – the highest achievement and reference point of procedural rights generally applicable in European administrative law⁶. Therefore, the focus was on the right to a hearing – including both personal hearing and written observations – the duty to state reasons and the right to access one’s file, and on a few selected the keywords⁷.

The research was based on a few choices. First, it covers legislation; however, only two types of legislative acts, directives

Integrated Administration (2009); C. Harlow-R. Rawlings (eds.), *Process and Procedure in EU Administration* (2014); C. Eckes, J. Mendes, *The Right to Be Heard in Composite Administrative Procedures*, 36 *Eur. L. Rev.* 651 (2011); H. Hofmann-M. Tidghi, *Rights and Remedies in Implementation of EU Policies by Multi-Jurisdictional Networks*, 20 *Eur. Pub. L.* 147 (2014).

³ At <http://eur-lex.europa.eu/>

⁴ P. Craig, UK, *EU and Global Administrative Law: foundations and challenges* (2015), 459-60. For some general remark see also M. Gnes, M. Macchia, *Administrative Procedure and Judicial Review in the European Union*, in G. della Cananea, M. Andenas (eds.), *Judicial Review of Administration in Europe: Procedural Fairness and Propriety* (2021), 45.

⁵ P. Craig, *Article 41 – Right to Good Administration*, in S. Peers-T. Hervey-J. Kenner-A. Ward (eds.), *The EU Charter of Fundamental Rights. A Commentary*, (2014), 1069-1098; I. Rabinovici, *The Right to be heard in the Charter of Fundamental Rights of the European Union*, 18 *Eur. Pub. L.* 149 (2012).

⁶ K. Kańska, *Towards Administrative Human Rights in the EU. Impact of the Charter of Fundamental Rights*, in 10 *Eur. L. J.* 296 (2004).

⁷ The keywords used were “access to file”, “statement of reasons”, with the variant “statement of the reasons”, and “right to a hearing” with the alternatives of “hearing of the parties”, “due process”, “notice and comment”. It must be highlighted that no record of the last of these was found by the search engine.

and regulations in force⁸, including executive and implementing⁹ ones, were considered. Decisions, instead, were not included, despite their possible normative content. The reason for doing so was, however, to maintain the focus on statutory pieces of legislation of general application¹⁰. Second, during the selection of the legislation to insert in the database it was also decided not to include all those where the mentioned keywords appeared only in the preamble¹¹.

This first, quantitative part of the research, is the basis to develop the second, focused on a qualitative insight into the collected data. The aim will be to provide a more in-depth inquiry into the legislation which has, in some way or another, interesting features. The relevance of the selected pieces of legislation was scrutinised using various criteria, which range from the subject matter of the rules, their quantitative relevance, their specific status (*e.g.*, their necessity, as it is for the financial rules), and their being frequently subject to the scrutiny of the European courts¹². This qualitative analysis will be dealt with in the second part of the paper.

⁸ A caveat is however required, as during the elaboration of data, the results of the research proved to have some faults, mainly due to the ability of the database to deliver an output exactly matching the query. This warning concerns an estimate of roughly 3% of pieces of legislation no longer in force, but which nevertheless appeared among the outcomes.

⁹ P. Craig, *Delegated Acts, Implementing Acts and the New Comitology Regulation*, 36 *Eur. L. Rev.* 671 (2011).

¹⁰ It is extremely important here to recall that the European Parliament conducted a “European Added Value Assessment” on a Law of Administrative Procedure of the European Union in 2012. The results highlighted an uncomfortable – though not surprising – situation where the most precise and comprehensive codification of administrative procedure within the EU can be found in the internal documents of the institutions, mostly based on the Ombudsman’s Code – in particular their Rules of Procedure – and in soft law documents, such as code of conduct, which are not legally binding.

¹¹ Therefore, only the regulating part of EU norms has been considered relevant to the purpose of the research since the preambles have the aim of simply providing the proper interpretative framework for end users.

¹² To this end reference is made to a previous work of the author, where case law concerning administrative procedural rights was the issue. L. Muzi, *Administrative due process of law in the light of the jurisprudence of EU Courts: a quantitative and qualitative analysis*, in C. Harlow-P. Leino-G. della Cananea (eds.), *Research Handbook on EU Administrative Law* (2017), 468.

2. Coping with an original absence: the birth of an EU administrative procedural law

Broadly speaking, the development of general principles structuring the EU administrative legal order has been undertaken by the European courts¹³. The same applies to the principle of due process in administrative proceedings. It was the Council of Europe, the first supranational institution at European level, to address the issue concerning fair administrative procedures with two resolutions¹⁴ which were meant to increase the protection of citizens' rights against phenomena of maladministration at national level. These efforts could draw more attention to this issue inside the European Union¹⁵ as well, and despite the acknowledgement of national procedural autonomy. Not surprisingly, the case law of the ECJ made several references to Articles 6¹⁶ and 13¹⁷ of the European Convention for the Protection of Human Rights and Fundamental Freedoms ("ECHR") during those years, to highlight the role of procedural rights in protecting the four freedoms laid down by the EEC Treaty¹⁸, though some of

¹³ Cf. J. Rivero, *Vers un droit commun européen: nouvelles perspectives en droit administratif*, in M. Cappelletti (ed.), *Nouvelles perspectives du droit commun de l'Europe* (1978), 389; T. Tridimas, *The General Principles of EU Law* (2006); C. Harlow, *Three Phases in the Evolution of EU Administrative Law*, in P. Craig, G. de Búrca (eds.), *The Evolution of EU Law* (2011), 439-464. Cf. also the notorious C-26/62 *Van Gend en Loos v Aministratie der Belastingen*, ECLI:EU:C:1963:1.

¹⁴ Resolution no. 31 of 28 September 1977 on the Protection of the Individual in Relation to the Acts of Administrative Authorities and Resolution no. 2 of 11 March 1980 on the Exercise of Discretionary Powers by Administrative Authorities

¹⁵ C. Harlow, *Codification of EC Administrative Procedures? Fitting the Foot to the Shoe or the Shoe to the Foot?*, in 2 *Eur. L. J.* (1996), 4.

¹⁶ Article 6 of ECHR (the right to a fair trial) states: "[i]n the determination of his civil rights and obligations or of any criminal charge against him, everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law".

¹⁷ Article 13 of ECHR (the right to an effective remedy) lays down: "[e]veryone whose rights and freedom as set forth in this Convention are violated shall have an effective remedy before a national authority notwithstanding that the violation has been committed by persons acting in an official capacity".

¹⁸ Among others, C-222/84, *Johnston v Chief Constable of the Royal Irish Constabulary*, ECLI:EU:C:1986:206, para. 18 and C-222/86, *UNECTEF v Heylens*, ECLI:EU:C:1987:442, para. 14.

them¹⁹ were already recognised by it.

Then, the preamble to the Maastricht Treaty clearly pointed out the importance of the rule of law²⁰ and set the goals of an enhancement of the democratic and efficient functioning of the institutions and of a decision-making process supposed to be as close as possible to citizens²¹. The Treaty of Amsterdam replaced this rather vague commitment with a clear duty, at Article 6 of TEU, to respect fundamental rights and stated for the very first time a right to access documents at the level of the treaties²².

2.1 A principle of and a right to good administration in the EU

In the Nice Treaty the protection of citizens' administrative procedural rights went one step further, when the Charter of Fundamental Rights of European Union ("CFR"), adopted there in 2000, enshrined, with Article 41, the right to a good administration²³. The CFR became binding only in 2009, with the entry into force of the Lisbon Treaty. Therefore, the EU now has a subjective public right to good administration²⁴ applied horizontally and standing beside the principle of sound (or good) administration. While Article 41 CFR serves to establish a minimum protection of certain elements generally accepted in the existing case law of the European courts, there still is a broader principle of fair administrative procedure, acknowledged by case law, which shall be respected beyond the narrower scope of application of the right in Article 41 CFR.

At present, their main difference relates to the limits of the protection offered: Article 41 CFR is applicable only to activity of the EU institutions and bodies, while references to good administration as a general principle also enable the European courts to invoke it against Member States when acting within the

¹⁹ E.g., the requirement for the statement of reasons and the duty to notify administrative decisions at Articles 190 and 191 EEC.

²⁰ C-294/83, *Les Verts v European Parliament*, ECLI:EU:C:1986:166, para. 23.

²¹ Article A of Treaty of Maastricht.

²² Cf. Article 255 TEU.

²³ P. Leino, *Efficiency, Citizens and Administrative Culture. The Politics of Good Administration in the EU*, 20 Eur. Pub. L. 681 (2014).

²⁴ K. Kańska, *Towards Administrative Human Rights in the EU. Impact of the Charter of Fundamental Rights*, cit. at 6, 300.

sphere of EU law²⁵, within composite or indirect administrative proceedings.

On the other hand, despite the principle of good administration having a wider field of application, it offers weaker safeguards to complainants. It is not – as such – justiciable²⁶ and its infringement could not be invoked by a claimant in front of an EU court without making a clear reference to one of its components²⁷. Besides this, the courts have a key role in defining the content and limits of every single procedural right referable to the principle of fair decision-making²⁸, because of the absence of a comprehensive act on EU administrative procedure. Lastly, provisions like those laid down by Article 41 CFR apparently show how “good administration” is largely an ungraspable concept²⁹.

The only other anchorage could be found where sector-specific legislation embraced procedural precepts from case law but, in these cases, the judicial principles are necessarily adapted

²⁵ H. Hofmann, G. Rowe, A. Türk, *Administrative Law and Policy of the European Union* (2011), 203.

²⁶ Case law has established that “the principle of sound administration, does not, in itself, confer rights upon individuals [...], except where it constitutes the expression of specific rights such as the right to have affairs handled impartially, fairly and within reasonable time, the right to be heard, the right to have access to files or the obligation to give reasons for decisions, for the purposes of Article 41 of the Charter of Fundamental Right of the European Union”. T-193/04 *Tillack v Commission*, ECLI:EU:T:2006:292, para. 127. Cf. also T-196/99 *Area Cova and others v Council and Commission*, ECLI:EU:T:2001:281, para. 43, “the applicants have not pleaded the infringement of a rule of law intended to confer rights upon individuals. The illegality they complain of, supposing it to be established, consists only in the infringement of the principle of sound administration”.

²⁷ AG Maduro pointed out the diversity between the duties and obligations of the Commission rooted in the principle of sound administration and the right to good administration in his opinion to the *max.mobil* case. There, he makes clear that such obligations cannot create a subjective right to intervene directly in a procedure, to obtain a decision or, consequently, a right to institute proceedings against that decision. C-141/02 P, *Commission v T-Mobile Austria GmbH*, ECLI:EU:C:2005:98, and opinion of AG Maduro, ECLI:EU:C:2004:646, paras. 55-56.

²⁸ K. Lenaerts, J. Vanhamme, *Procedural Rights of Private Parties in the Community Administrative Process*, cit. at 1, 568.

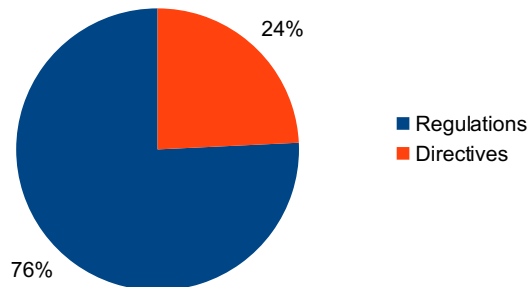
²⁹ R. Bousta, *Who Said There is a ‘Right to Good Administration’? A Critical Analysis of Article 41 of the Charter of Fundamental Rights of the European Union*, 19 Eur. Pub. L. 481 (2013).

to the specific context where they would apply. This being the case, the margin of judicial interpretation of procedural rights would be narrower and would be limited to checking the fair application of legislative provisions.

To summarise, like a Cubist painting, the picture that emerges from this portrait is extremely fragmented and abstract, without any hint of perspective. Nevertheless, it is well known which role procedures play during the exercise of authoritative powers. To some extent, they could be even more important than substantive law³⁰ because the way procedures are drawn up can affect the outcome of the decision-making process to a significant degree³¹. It is no mystery that the legislator can adapt the procedures significantly to address the various – private and public – interests which are meant to be protected and to achieve its policy goals. However, this issue will be dealt with in the second part of this paper while the focus now turns to some quantitative data.

3. A quantitative analysis of due process rights in sector-specific legislation

From a quantitative viewpoint, the very first and most apparent data is the overabundance of regulations in comparison with directives. This outcome seems to be self-explanatory in the light



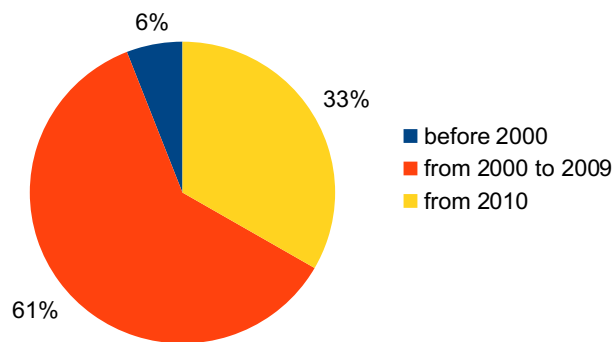
of the principle of the procedural autonomy of member states. In most cases – and according to that long-established principle – when the piece of legislation adopted is a directive every state is free to determine how to reach the given policy goals. On the contrary, when dealing with regulations – being self-applicable

³⁰ J. Lever, *Why Procedure is More Important than Substantive Law*, Int'l. & Comp. L. Q. 285 (1999).

³¹ G. della Cananea, *Due Process of Law Beyond the State: Requirements of Administrative Procedure* (2017), 7-8.

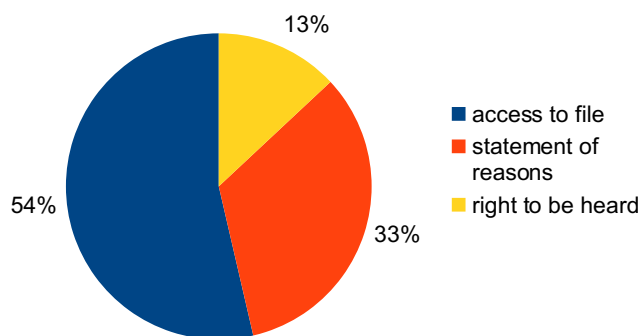
acts – the EU legislator may give a clear set of provisions both on the substantial and on the procedural side of the matter that is being dealt with.

When considering the timing of the adoption of the relevant legislation, most of it has been adopted during the decade from 2000 to 2009. However, comparing that number with the provisions enacted in the seven years from 2010 to 2016, it might be possible to foresee a comparable



trend in the current decade. As concerns legislation enacted before 2000, the very low number of acts could be explained by at least two main reasons. First and foremost, it is reasonable to state that not many provisions adopted nearly twenty years ago are still in force, because of a normal rate of replacement of laws over the years, according to the evolving needs of any society. It also needs to be recalled that the adoption of the Charter of Fundamental Rights in 2000, with its Article 41, must be considered the tip of the iceberg of a long process of the acknowledgement of procedural rights as key features of the functioning of the EU legal order, as the previous paragraphs tried to explain. Therefore, before that year, there was undoubtedly a growing, but not still pervasive understanding of the need to address procedural requirements in decision-making within the boundaries of the EU administrative order.

Quite surprisingly, when looking more closely at the selected legislation), the most striking outcome is that only a very low percentage of proceedings mentions the right to a hearing. Probably, the reason lies in the acknowledgment of a far-



reaching principle of the right to defence that also encompasses the right to a hearing, which must be applied even though it is never mentioned in the provisions applicable to the case. On the other hand, most of the legislation analysed makes a brief reference to access to files and regulation 1049/2001, sometimes stating a commitment to transpose this right into internal regulations. As far as statements of reasons are concerned, a third of the legislative acts taken into consideration have a provision regarding this. This data should be compared with the much lower number of clauses concerning the right to a hearing, being the twin rights of the same principle. However, it seems to be hard to find a clear and satisfying explanation for this gap.

4. Efforts to achieve codification

So far, when adopting a decision affecting the interests of private parties, the EU authorities apply sector-specific legislation which often lays down not only substantive, but also procedural rights. The content of procedural rights has been developed by courts on a case-by-case basis, and the precepts laid down in the judgments have then been translated into secondary legislation and modelled in such a way as to fit the specificities of the area. When a *lacuna* on the procedural side occurs, the unwritten general principles of fair decision-making must be observed in order not to impinge on the legality of the decision adopted as a result of those proceedings. These principles are grounded in the legal traditions common to the Member States³² and they took their legitimisation from there³³.

4.1 The proposal of the European Parliament for a regulation

The idea of a codification of EU administrative procedure made its first appearance in the mid-1990s³⁴ but the project actually began with the Research Network on EU Administrative

³² C-17/74, *Transocean Marine Paints Association v Commission*, ECLI:EU:1974:106, opinion of AG Warner, ECLI:EU:C:1974:91.

³³ Cf. J.A. Usher, *The Influence of National Concepts on Decisions of the European Court*, 1 Eur. L. Rev. 371 (1976).

³⁴ Cf. C. Harlow, *Codification of EC Administrative Procedures? Fitting the Foot on the Shoe or the Shoe on the Foot*, 2 Eur. L. J. 3 (1996).

Law (“ReNEUAL”)³⁵. This multinational group of academics was motivated by the acknowledgement of a certain widespread distrust towards an administrative system where the rules on basic procedural issues are difficult to discern for the individual claimant and where administrators and draft legislators have to assemble a new package of procedural rules on each occasion. Therefore, the aim of the Model Code was – in their authors’ minds – to improve the existing regime without eliminating the peculiarities of sector-specific legislation, but rather filling the gaps by putting together a boilerplate general law like the one proposed.

To reduce the fragmentation of the applicable law and foster compliance with the general principles of EU law, the European Parliament finally reached the decision to submit to the Commission a proposal of a regulation on administrative procedure drawing on the work of ReNEUAL³⁶. As is made clear from the title³⁷, the field of application of the proposal is limited to administrative procedures implemented by EU authorities in “direct administration” and “composite procedure”³⁸, thus excluding not only the administrative procedure of the Member States but also legislative and judicial proceedings³⁹.

³⁵ E. Chiti, *Adelante, con juicio: la prospettiva della codificazione del procedimento europeo*, *Gior. dir. amm.* 677 (2014).

³⁶ D.U. Galetta, H. Hofmann, O. Mir and J. Ziller, *Context and Legal Elements of a Proposal for a Regulation on the Administrative Procedure of the European Union’s Institutions, Bodies, Offices and Agencies*, *Riv. It. Dir. Pub. Com.* 312 (2016).

³⁷ “Proposal for a Regulation of the European Parliament and Council on the Administrative Procedure of the European Union’s institutions, bodies, offices and agencies”, which reproduces exactly the wording of Article 298 TFEU. The latter states “[i]n carrying out their mission, the institutions, bodies, offices and agencies of the Union shall have the support of an open, efficient and independent European administration. [...] the European Parliament and the Council, acting by means of regulations in accordance with the ordinary legislative procedure, shall establish provisions to that end”.

³⁸ Following Recommendation 1 annexed to European Parliament resolution EP 2012/2024.

³⁹ Delegated and implementing acts are also excluded. Therefore, the Proposal of the European Parliament has a narrower field of application in comparison with the Model Code of ReNEUAL, being directed only to individual decision-making. The Model Code instead also lays down rules on administrative rule-making, contracts, mutual assistance and administrative information management. More details can be found at <http://www.reneual.eu/>. Cf. also C. Harlow-R. Rawlings, *Process and Procedure in EU Administration* (2014), 331-

The goal of this proposed piece of legislation is to enhance legal certainty thanks to a specification of rights and duties and a simplification of the overall legislation dealing with procedural aspects of a particular complexity⁴⁰. Furthermore, the aim of the proposal is to contribute to the compliance with principles of due process, trying to achieve a difficult balance between effectiveness in everyday administrative practice and the protection of individual rights. Finally, the definition of general rules on administrative procedure provides an opportunity to define a common parameter for the regulation of relations between citizens and public authorities.

However, the Commission has so far shown a cautious or, rather, reluctant attitude towards the resolution of the European Parliament soliciting a proposal for legislation grounded in Article 298 of the Lisbon Treaty. Despite the alleged readiness of the Commission to continue working with the Parliament in refining, improving, and streamlining EU administrative law and its openness, it admittedly still must be convinced about the opportunity of legislation providing for a horizontal framework⁴¹, not being able yet to see the added value of such a proposal.

4.2 Sector-specific legislation

Broadly speaking, discretionary powers ought to be subject to procedural requirements to provide a proper balance between the primary interest of the administration and the secondary interests - both public and private - involved in the proceeding. Any decision-maker, complying with their duty to provide sound administration, ought to hear evidence and consider the affected parties' observations, performing with due diligence a so-called "interest representation model", which is meant to be better able than the political process to determine the most suitable decision

335, which considers the legislation contained in the proposal as "minimalist" and "residual".

⁴⁰ On this issue, cf. S. Cassese, *Legislative Regulation of Adjudicative Procedures: An Introduction*, Eur. Rev. Public L. 15 (1993), and J. Barnes, *Towards a third generation of administrative procedure*, in S. Rose-Ackerman-P. Lindseth (eds.), *Comparative Administrative Law* (2010), 336.

⁴¹ Cf. the laconic answer given by First Vice President Timmermans on behalf of the Commission to a Parliamentary question on the Law of Administrative Procedure of the European Union on 11th May 2016, E-001249/2016.

in any case⁴². Moreover, a fair hearing could not take place if the parties are not allowed to view all the relevant information in their own file, and therefore no arbitrary limitation to scrutiny can be put in place by the deciding authority on the evidence used during the proceeding.

Only by complying with these procedural rules will the deciding authority be steered to a correct decision-making process, the most internalised and hidden features of which finally must be explained in a statement of reason. The latter is the tool the affected parties can rely on to have an insight into (all) the phases of the process and evaluate whether to bring an action against the decision or to ask for a review of the final decision⁴³.

The most important consequence of the absence of an all-embracing code of administrative procedure is the extremely low degree of transparency of procedural rights and obligations in administrative decision-making. Any infringement of an essential procedural requirement obviously allows the decision to be annulled⁴⁴ and claimants can refer to the principle of administrative due process or, since 2000, to Article 41 CFR, which enshrines a still very general right to good administration. But when facing more detailed provisions, it becomes quite an undertaking to evaluate their fair enforcement by public authorities. It should also be stressed that sector-specific legislation and practices on administrative procedure often differ from one another. Broadly speaking, secondary rules try to forge their own procedural standards, mainly to address the interests of the parties concerned. In some other cases, the legislator's aim is to

⁴² G. Della Cananea, *Beyond the State: the Europeanization and Globalization of Procedural Administrative Law*, 9 Eur. Pub. L. 577 (2003).

⁴³ Cf. L. De Lucia, *A Microphysics of European Administrative Law: Administrative Remedies in the EU after Lisbon*, 20 Eur. Pub. L. 277-308 (2014). It must be recalled that recently several agencies have been equipped with boards of appeal in order to provide independent administrative reviews of first-instance hi-tech and scientifically complex decisions. For further reading cf. M. Navin-Jones, *A Legal Review of EU Boards of Appeal in Particular the European Chemicals Agency Board of Appeal*, 21 Eur. Pub. L. 143-68 (2015); L. Bolzonello, *Independent Administrative Review Within the Structure of Remedies under the Treaties: The Case of the Board of Appeal of the European Chemicals Agency*, 22 Eur. Pub. L. 569-82 (2016); M. Eliantonio, M. Chamon, A. Volpato, *Boards of Appeal of EU Agencies: Towards Judicialization of Administrative Review?* (2022).

⁴⁴ Article 263 TFEU.

establish *ad hoc* tailored procedural frameworks consistent with the subject matter at stake. Nevertheless, the way in which rules are applied practically may diverge to a certain extent from the positive provisions, making it even harder to assess whether the public official acted fairly.

5. Procedural rights: a comparison

The chart below summarises the content of the qualitative analysis which will be carried out in the following paragraph. Starting from the Model Code of ReNEUAL and the proposal of the European Parliament for an administrative procedure act, thirteen procedural safeguards have been selected which roughly correspond to the procedural steps common to many domestic laws on administrative procedures. In a second moment, these were matched with sector-specific legislation, to try to find out whether and how they were inserted and contextualised into the applicable, living rules of procedure⁴⁵. In order to select the pieces of legislation to analyse, a further step was made by cross-checking the rules with case law and European Ombudsman inquiries⁴⁶ concerning the procedural guarantees enshrined in the legislative acts in question⁴⁷. In some cases, the pieces of

⁴⁵ A similar analysis can be found in L. Saltari, A. Salvato, *Frammentazione dei procedimenti amministrativi di settore. Verso un loro completamento grazie ad una codificazione generale?*, in G. della Cananea, M. Conticelli (eds.), *I procedimenti amministrativi di adjudication dell'Unione europea: principi generali e discipline settoriali* (2017), 121.

⁴⁶ Cf. S. Cadeddu, *The Proceedings of the European Ombudsman*, in 68 *Law & Contemp. Probs.* 161 (2004) where the author labels the European Ombudsman as a "codifier of good administration". The target of the European Ombudsman's mandate is to detect "maladministration", a concept that encompasses failure to respect the law, failure to respect fundamental rights and the principles of good administration. It has the power to suggest both redress for individual cases and modifications to laws and administrative practices. For a more recent reading of the European Ombudsman's role cf. R. Rawlings, *Complaints system and EU governance – a new look*, in *Research Handbook on EU Administrative Law*, cit., part. 497.

⁴⁷ On the alternative use of the Ombudsman and judicial complaints cf. P.N. Diamandouros, *Legality and good administration: is there a difference?*, in J-P. Delevoye, P.N. Diamandouros (eds.), *Rethinking good administration in the European Union* (2008). Cf. also J. Söderman, *A Thousand and One Complaints: The European Ombudsman en Route*, 3 *Eur. Pub. L.* 351-361 (1997).

legislation encompass rules on more than just one administrative proceeding, therefore each of them was separately analysed and reported in the chart below.

	Right to receive		Duty of careful investigation			Duty to cooperate		Right to be heard	Right to access the file	Right to be given reasons for final decision	Right to respect linguistic identity	Duty to deliver the decision within time-limits	Reference to due process principles
	a notice	acknowledgment of receipt	hear evidence	request documents	carry out inspections	Reasonable time-limit to reply	Right against self-incrimination						
ReNEUAL's Model Rules	Art.III-5	Art.III-6	Art. III-13	Art. III-10	Art.III-16 ff.	Art.III-11	Art.III-14	Art.III-23 ff.	Art.III-22	Art.III-29	Art.III-31	Art. III-9	
EP proposal of APA	Art. 6	Art. 7	Art. 9	Art. 9	Art. 12	Art. 10	Art. 10	Art. 14	Art. 15	Art. 19	Art. 6	Art. 17	
Council Regulation (EC) No 1005/2008 ⁴⁸	Art. 23	x	Art. 10	Art. 10	Art. 10	Art. 26	x	Art. 27	x	Art. 26/27	x	x	
Council Regulation (EC) No 207/2009 ⁴⁹	Art. 79	x	Art. 78	Art. 78	x	x	x	Art. 77	Art. 123	Art. 75	Art. 119	x	Art. 83

⁴⁸ Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999. See also Commission Regulation (EC) No 1010/2009 of October 2009, laying down detailed rules for the implementation of Council Regulation (EC) No 1005/2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing.

⁴⁹ Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trademark.

	Right to receive		Duty of careful investigation			Duty to cooperate		Right to be heard	Right to access the file	Right to be given reasons for final decision	Right to respect linguistic identity	Duty to deliver the decision within time-limits	Reference to due process principles
Regulation (EC) No 1907/2006 50													
registration	x	Art. 20,1	x	Art. 20,2	x	Art. 20,2	x		Art. 118	Art. 130	x	Art. 21	x
evaluation	Art. 50,1	x	x	Art. 41,3 Art. 46,1	x	Art. 41,4 Art. 46,2	x	Art. 50,1	Art. 118	Art. 130	x	Art. 43,1 Art. 46,3	x
authorisation	x	Art. 64,1	x	Art. 64,3	x	Art. 64,3 Art. 64,5	x	Art. 64,5	Art. 64,2 Art. 118	Art. 64,9 Art. 130	x	Art. 64,8	x
restriction	x	x	x	Art. 69,4	x	Art. 69,4	x	Art. 69,6	Art. 118	Art. 130	x	Art. 73,1	x
Council Regulation (EC) No 1/200351	x	x	Art. 27	Art. 27	Art. 20-22	Art. 27		Art. 27	Art. 27				

⁵⁰ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

⁵¹ Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Art. 81 and 82 of the Treaty.

	Right to receive		Duty of careful investigation			Duty to cooperate		Right to be heard	Right to access the file	Right to be given reasons for final decision	Right to respect linguistic identity	Duty to deliver the decision within time-limits	Reference to due process principles
			Art. 9,2	Art. 3,1	Art. 9,4	Art. 9,2	Art. 9,4						
Regulation (EU, Euratom) No 883/2013 ⁵²		x	Art. 9,2	Art. 3,1	Art. 9,4	Art. 9,2	Art. 9,4		Art. 11,1	x		x	
Council Regulation (EU) No 1024/2013 ⁵³	x	x	Art. 11	Art. 10	Art. 12	x	x	Art. 22	Art. 22	Art. 22	x	x	x
Regulation (EC) No 1107/2009 ⁵⁴	Art. 9,1	x	Art. 13	Art. 12,3	Art. 68	Art.9,2	x	Art. 11,3 e 12,3	Art. 10	Art. 13,1	x	various	x
Regulation (EC) No 1829/2003 ⁵⁵	x	Art. 5,2	x	Art. 6,2	x	Art. 6,2	x	x	Art. 29	Art. 7	x	Art. 6	x
Directive 2001/18/EC ⁵⁶	x	Art. 6,5	x	Art. 15,1	Art. 5,5	x	x	x	Art. 9 e 24	Art. 15,2	x	Art. 6	x

⁵² Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999.

⁵³ Council Regulation (EU) No 1024/2013 of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions.

⁵⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

⁵⁵ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

⁵⁶ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organism and repealing Council Directive 90/220/EEC.

6. The economic interests within the EU

6.1 The procedure safeguarding intellectual property

Council Regulation (EC) no. 207/2009 of 26 February 2009 on the Community trademark rules on various procedures before the European Union Intellectual Property Office (EUIPO)⁵⁷, and more specifically on registration, opposition, renewal, revocation or declaration on invalidity and appeals relating to the European Union trademark. Notwithstanding that piecemeal procedural issues are spread throughout the text, Title IX is completely dedicated to setting general provisions concerning the procedures of EUIPO.

Article 75 specifies that the Office shall state reasons upon which its decisions are based and on which the parties concerned have had an opportunity to present their comments. Oral proceedings (Article 77) could be held at the instance of the Office or at the request of any party to the proceeding whenever the Office considers them expedient. As a rule, they shall be public only if they are second instance procedures and if they did not imply serious and unjustified disadvantages for a party to proceedings. Moreover, other details concerning the hearing can be found at Article 78 dealing with the investigative phase of the administrative procedure and, more precisely, the cross-examination of witnesses and experts. On the other side of the coin, when considering time limits, Regulation no. 207/2009 makes a *renvoi* to the delegated acts to be adopted by the Commission which specifies details regarding their calculation and duration. Finally, it is worth mentioning that Article 83 lays down that, whenever a regulatory vacuum occurs, reference shall be made to principles of procedural law generally recognised in the Member States.

6.2 The budgetary interest of the EU: the Financial Regulation

The Financial Regulation⁵⁸ of the European Union offers

⁵⁷ On procedures before the agencies of EU cf., among others, E. Chevalier, *La procédure devant les agences de l'Union européenne*, in J.B. Auby, T. Perroud (eds.), *Droit comparé de la procédure administrative* (2016), 565-77.

⁵⁸ Regulation (EU, EURATOM) no. 966/2012 of the European Parliament and Council of 25 October 2012 on the financial rules applicable to the general

some other opportunities to reflect on procedural standards, considering that Article 41 of the CFR applies to it⁵⁹. As mentioned above, this piece of legislation catches the observer’s attention mainly due to its special status determined by its necessity to the Union machinery⁶⁰. At present, it is the reference point⁶¹ for the principles and procedures governing the establishment, implementation, and control of the EU budget. Therefore, rules of procedure are spread throughout the text, even though there is a chapter dedicated to “Administrative principles” within Title IV, concerning “Implementation of the budget”; here, the heading of Article 96 refers to “good administration”.

However, this article only concerns award procedures and it lays down precepts relating to the request of documents within the assessment of proposals. More specifically, the responsible authorising officer has the duty to make known to the applicant, without delay, the need to supply evidence and/or documents, their form and prerequisite contents, and an indicative timetable for doing so. In those cases where the applicant’s failure to submit evidence or make statements is only due to clerical errors, the authorising officer or the evaluation committee shall ask the applicant to provide for the missing documents or information, making it clear that no substantial changes must occur to the original proposal.

The only provision explicitly mentioning a duty of the Commission to state reasons is Article 38, para. 3, lett. d, which concerns the funding of international organisations. In these cases, the Commission is required to attach to the draft budget a working document also containing the reasons why it was more

budget of the Union and repealing Council Regulation (EC, EURATOM) no. 1605/2002.

⁵⁹ Cf. The European Ombudsman's “Response to the Public Consultation on Review of the Financial Regulation” of 17 December 2009 issued as a preliminary work to the second review of the Financial Regulation in 2012, at https://www.ombudsman.europa.eu/resources/otherdocument.faces/en/4957/html.bookmark#_ftnref5.

⁶⁰ P. Craig, *A New Framework for EU Administration: The Financial Regulation 2002*, 68 *Law & Contemp. Probs.* 107-134 (2004).

⁶¹ Together with Commission Delegated Regulation (EU) no. 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, EURATOM) no. 966/2012 of the European Parliament and Council on the financial rules applicable to the general budget of the Union.

efficient for the Union to fund those international organisations rather than act directly. Here, the duty to state reasons is applied to make clear the evaluations behind a purely discretionary choice⁶² linked to the distribution of funding.

As far as the right to be heard is concerned – not surprisingly – perhaps the most interesting rules concern the shared management of the budget (Article 59) which implies that implementation tasks are delegated to Member States. In playing this role, Member States are subject to several accounting duties and to the scrutiny of the Commission, which can even interrupt payment deadlines or suspend payment where so provided in sector-specific legislation. However, the Commission shall end all or part of the interruption of payments as soon as a Member State has taken any measure to resolve the problem and submitted its observations. Therefore, this provision confirms the importance of allowing a sanctioned party to explain its reasons, this being the only efficient way to ensure a correct evaluation of all the interests involved in using the budget.

Some very interesting procedural provisions can also be found under Title VI, concerning grants. Article 135 regards payment of grants and controls, specifically pointing to the problem of a grant already awarded but award or implementation procedure of which prove to have involved substantial errors, irregularities, fraud, or breach of obligations. In these circumstances, the authorising officer may, provided that the applicant or beneficiary has been given the opportunity to make observations, refuse to sign the grant agreement, suspend implementation of the grant, or terminate the grant agreement. In cases where such irregularities are attributable to the beneficiary, or the beneficiary has broken their obligations under a grant agreement, the authorising officer could even decide to reduce the grant or recover amounts unduly paid, but in any case, the beneficiary must be given the opportunity to make observations.

Also, when systemic or recurrent errors, irregularities, fraud, or breach of obligations are shown at the end of controls or audits, the authorising official can adopt sanctions ranging from suspension to terminating the grant agreement, though not before

⁶² On the intertwinement of discretionary powers and administrative procedures cf. G. della Cananea, *Beyond the State: the Europeanization and Globalization of Procedural Administrative Law*, 9 Eur. Pub. L. 563 (2003).

having given the beneficiary the opportunity to make their observations during a hearing. Moreover, the beneficiary must be given the chance to be heard regarding the method of extrapolation used or the flat rate applied to determine the amounts to be reduced or recovered whenever it should not be feasible to precisely quantify them.

6.3 The procedural powers of OLAF

A core role within this subject is played by Regulation no. 883/2013 which is applied during proceedings related to the fight against fraud, corruption and any other illegal activity affecting the financial interests of the Union being, as such, inherently linked to the Financial Regulation. This piece of legislation repealed and replaced Regulation (EC) no. 1073/1999⁶³ in order to make the activity of OLAF more effective, especially broadening its investigative powers both internally and externally.

External and internal investigations follow, in part, different rules. However, OLAF is allowed to combine external and internal aspects in a single investigation without having to open two separate investigative procedures. Procedural rights applicable to investigations are specified in the interest of legal certainty. Information should be treated in accordance with Union law on data protection⁶⁴, legitimate rights and procedural guarantees of the persons concerned, including the right not to self-incriminate. Conclusions referring to a person concerned by name should not be drawn, at the final stage of an investigation, without that person being given the opportunity to comment on facts concerning them, thus respecting the right of the person affected by the decision to be heard.

Reference to OLAF rules of procedures allows for a better understanding of a case decided by the European Ombudsman in the complaint 1871/2014/EIS concerning the handling by the European Commission of a request for access to documents

⁶³ Regulation (EC) no. 1073/1999 of the European Parliament and Council adopted to regulate investigations conducted by the European Anti-Fraud Office

⁶⁴ Regulation (EC) no. 45/2001 of the European Parliament and Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

following a fraud investigation. The complainant's concern was to have – among other things – their right to access their own file fully respected, claiming they had been given the chance only to apply for public access to the files according to Regulation 1049/2001. The Ombudsman decided that, when a request to access a file concerns decisions which adversely affect the interests of those seeking access, that request shall be assessed under Article 41, 2 of the Charter instead of Regulation 1049/2001. In settling the case, the Ombudsman made it clear that access according to Article 41, 2 CFR “would never be narrower than the access granted under Regulation 1049/2001 and may well, depending on the specific content of the documents, be broader”⁶⁵. Therefore, the Commission, in failing to do so, was responsible for maladministration because, due to its behaviour, it gave rise to a material limitation of a fundamental right.

7. The interest connected to the environment and citizens' health

7.1 Authorisation of pesticides

The placing of plant-protection products on the market is another interesting procedure, governed by Regulation no. 1107/2009 aimed at removing obstacles to trade due to different levels of protection in Member States, to harmonise rules for the approval of active substances and the placing on the market of plant-protection products, including rules on the mutual recognition of authorisations and parallel trade. The decision on acceptability or non-acceptability of such substances is to be taken at EU level based on harmonised criteria.

A very detailed procedure concerns the assessment of the approval of an active substance. A first evaluation of the information provided by the interested parties is carried out by the Member State where the application is submitted, then a risk assessment is performed by the European Food Safety Authority, while a risk management assessment is performed by the

⁶⁵ Decision of the European Ombudsman in complaint 1871/2014/EIS concerning the handling by the European Commission of a request for access to documents following a fraud investigation of 15 March 2016, para. 29.

Commission which also makes the final decision regarding the active substance.

After this first procedure, any pesticide must have its approval renewed after a given time. Applications for renewal of approval are evaluated first by a rapporteur Member State and afterwards a peer review is carried out by the EFSA and other Member States. Whenever a producer of an active substance wants to obtain a renewal of the authorisation, they must submit an application to the designated rapporteur Member State (RMS) which will draft a Renewal Assessment Report (RAR). The Report is then submitted to EFSA which will peer review it in cooperation with the remaining Member States. During this phase, EFSA might organise a public consultation on the Report if asked to do so by any interested party⁶⁶. Afterwards, EFSA drafts a scientific report which is submitted to the Commission, the final decision of which on the renewal of the approval needs to consider the conclusions of EFSA.

One of the most controversial provisions is that included in Article 17, where it is laid down that, when the duration of the procedure on renewal of the approval of an active substance is likely to expire before a decision is taken, the time limit for the decision can be extended on the basis of certain criteria. This could have dangerous effects on the environment and human health (it could even represent a breach of the precautionary principle). Glyphosate, an active substance suspected of being carcinogenic⁶⁷, for which the Commission decided to extend approval by 18 months after Member States failed to achieve a qualified majority

⁶⁶ Cf. Article 15(2) of Commission Regulation (EU) no. 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances, as amended by Commission Implementing Regulation (EU) no. 380/2013 of 25 April 2013 amending Regulation (EU) no. 1141/2010 as regards the submission of the supplementary complete dossier to the Authority, the other Member States and the Commission. On this issue the European Ombudsman delivered a decision in case 952/2014/OV on the public consultation procedure of the European Food Safety Authority for the renewal of the approval of the herbicide glyphosate where, however, it was affirmed that no breach of the right to participate in a public consultation could be found.

⁶⁷ The International Agency for Research on Cancer (IARC) judged it to be “probably carcinogenic”. Cf. IARC, 2015, ASB2015-8421.

for or against the Commission proposal, has demonstrated this very clearly.

7.2 GMOs

Another sensitive administrative procedure concerning EFSA is laid down in Regulation (EC) no. 1829/2003 of the European Parliament and Council of 22 September 2003 on genetically modified food and feed, which establishes a single EU authorisation procedure for feed consisting of, containing, or produced from GMOs.

The cornerstone idea relating to genetically modified food and feed is that they should be authorised for placing on the EU market only after scientific evaluation. This must be undertaken under the responsibility of the European Food Safety Authority and has to detect any risk which GMOs could present for human and animal health and, if applicable, for the environment. The scientific evaluation should be followed by a risk management decision by the EU, under a regulatory procedure ensuring close cooperation between the Commission and the Member States⁶⁸.

An application shall be sent to the national competent authority of a Member State which shall acknowledge receipt of the application within 14 days, inform EFSA and make the application available to it. EFSA informs the other Member States and the Commission of the application, making all the information available to them, as well as making a summary of the dossier available to the public. In the case of GMOs or food containing or consisting of GMOs, the application shall be accompanied by the technical dossier required to carry out the environmental risk assessment according to Directive 2001/18/EC⁶⁹ or a copy of the authorisation and a monitoring plan for environmental effects.

According to Article 6, EFSA has 6 months from the receipt of the application to give its opinion, and the time limit shall be extended whenever supplementary information is sought. To

⁶⁸ M. Weimer, *Risk Regulation and Deliberation in EU Administrative Governance – GMO Regulation and Its Reform*, 21 Eur. L. J. 627 (2015).

⁶⁹ Directive 2001/18/EC lays down a procedure on the deliberate release into the environment of GMOs which is an alternative to the environmental risk assessment ruled by this Regulation when products containing or consisting of genetically modified organisms are concerned. In any case, the national competent authorities have to be consulted by the Authority.

prepare its opinion it may ask a food assessment body from a Member State to carry out a safety assessment of the food, and might also ask the competent authority of a Member State to carry out an environmental risk assessment according to Directive 2001/18/EC. EFSA forwards its opinion to the Commission, the Member States and the applicant, attaching a report describing its assessment of the food and stating the reasons for its opinion and the information on which this opinion has been based, including the opinion of the competent authorities, when consulted.

Within three months of receiving the opinion of EFSA, the Commission shall submit (Article 7) a draft of the decision to be taken to the Committee on the Food Chain and Animal Health. When the draft decision is not in accordance with the opinion of EFSA, the Commission shall provide an explanation for the difference. A final decision shall be adopted according to the regulatory procedure laid down by Article 5 of Decision 1999/468/EC and – at this final point – the Commission shall without delay inform the applicant of the decision taken.

The General Court had been asked to give its judgment on the application of this regulation in Case T-177/13 by three German non-governmental organisations. They went before the court to annul the dismissal of their request for an internal review of the decision of the Commission to authorise the placement on the food market of ingredients containing, consisting of, or produced from modified soybeans. That was the first time that the General Court ruled on a decision adopted by the Commission further to a request for internal review under “the Aarhus Regulation”⁷⁰. However, the General Court rejected the argument put forward by the applicants, and precisely that the decision of the Commission would have been vitiated by a failure to state reasons. Not only did the judges consider the latter appropriate to the act in question, but the statement of reasons was considered capable of disclosing, in a clear and unequivocal fashion, the reasoning followed by the Commission so to enable the persons concerned to ascertain the reasons for the measure and the court to exercise its power of review.

⁷⁰ Regulation (EC) No 1367/2006 of the European Parliament and of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies.

Admittedly, it was the judgement itself that made clear, at para. 130, that the statement revealing the reasons for the decision should not go into all the relevant facts and point of law, since the question of whether it meets the requirements of the second paragraph of Article 296 TFEU must be assessed with regard not only to its wording, but also its contexts and all the legal rules governing the matter in question. Therefore, according to the judges, the Commission is not obliged to adopt a position on all the arguments submitted by the parties concerned, and it is sufficient if it sets out the facts and legal considerations having decisive importance in the context of the decision. The General Court concluded that the reasons given in the contested decision enable the applicant to understand why the Commission, in the exercise of its “broad discretion”, rejected its argument. In other words, the judges decided not to interfere with the position adopted by the deciding authorities, most likely due to the complexity of the procedure concerning a highly technical evaluation and considering satisfying the reasons given to the claimant despite them not answering each of the observations submitted.

7.3 Paediatric pharmaceuticals

Regulation no. 1901/2006 lays down dispositions concerning medicinal products for paediatric use the aim of which is to improve the availability of pharmaceuticals for children, in order to meet the specific therapeutic needs of sick children. As a rule, pharmaceutical companies have to carry out a Paediatric Investigation Plan (PIP) to ascertain whether and how their products – intended for adults – could be used to treat children’s diseases. However, the European Medicines Agency has the discretionary power to waive this duty under certain conditions to ensure that research, and funding, concerning children are channelled to meet their actual therapeutic needs.

Within this procedure a key role is played by the Paediatric Committee, which must issue an opinion on a Paediatric Investigation Plan (PIP) submitted by the interested party. When a PIP is submitted by a pharmaceutical firm in relation to a particular product, a receipt of application is sent by EMA. At first, the Agency verifies within 30 days if all the necessary data has been provided and when this is not the case, additional data is asked for. Then a rapporteur is appointed who shall deliver an

opinion in 60 days. The rapporteur can ask for a meeting and/or for additional data and make a request of changes to the plan.

The rapporteur transmits the dossier to the Paediatric Committee, which must rely on the rapporteur's preliminary investigation to deliver its opinion. The latter is used by EMA to adopt a draft decision either oriented to PIP adoption or the granting of a waiver. Before being adopted, each draft decision is transmitted to the applicant who has 30 days to ask for a re-examination. Whenever such a request is submitted, a new rapporteur is appointed and a supplementary investigation of a maximum of 30 days is carried out, eventually leading to supplementary data requests and new meetings. A final decision is transmitted to the applicant within 10 days from the end of the investigative phase.

In a case decided in 2013⁷¹ concerning a procedure on medicinal products for paediatric use⁷², though the Ombudsman considered that EMA was fully entitled to deny a waiver, they also found that the Agency was not able to grant suitable transparency throughout the procedure and failed to provide the reasons for its decision. The Agency was blamed not having acted fairly because it considered in different ways three similar applications for a product-specific waiver, all belonging to the same therapeutic class of medicinal substances and approved for the indication of heart failure in adults. In its statement of reasons, EMA, requiring only one of the applicants to conduct a paediatric study on heart failure, justified its decision referring not to the safety or efficacy of the product, but to its more pleasant taste. Therefore, the interested party submitted a claim to the European Ombudsman arguing that EMA was unable to ground its decision on an objective and fair assessment⁷³. The Ombudsman found that the Agency was not able to clearly state its reasons, for the version

⁷¹ European Ombudsman case: 2575/2009/(TS)(TN)RA against the European Medicines Agency, decided on 22 July 2013

⁷² Regulation (EC) no. 1901/2006 of the European Parliament and Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) no. 1768/2002, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.

⁷³ The decision should have to be considered arbitrary, considering how scientifically challenging a clinical study in paediatric heart failure would be due to the limited number of patients in the target population to be potentially enrolled.

publicly available of the decision made just a general and formal reference to the relevant grounds provided by the law to grant a waiver (Article 11) without specifying the reasons justifying it. In their draft recommendation to the Agency, the Ombudsman asked for the drafting of guidelines aimed at assisting the Paediatric Committee in its evaluative work and to provide the complainant with an adequate and consistent statement of reasons.

Therefore, this case shows that, even though Regulation no. 1901/2006 lays down a very detailed procedure when EMA is concerned with a market authorisation for a paediatric pharmaceutical, it nevertheless was unable to match its decision with an exhaustive statement of reasons. The grounds for the Ombudsman's recommendation were the need for clearer rules of procedure for its consultative body, the Paediatric Committee, whose work is at the root of the final decision of the Agency and whose lack of clarity had led to incomprehensible decisions from the applicant's point of view.

7.4 Marketing of chemicals

The REACH regulation (EC 1907/2006) lays down specific duties and obligations on manufacturers, importers, and downstream users of substances *i.e.*, chemical elements, (on their own, in preparations and in articles) to prevent adverse effects on human health and the environment. REACH oversees four different processes, namely the registration, evaluation, authorisation, and restriction of chemicals to ensure high levels of human health and environmental protection in all Member States. The decision-making process is led by specific due process rights and in some cases, according to Article 93, before submitting a claim to the judiciary, an internal review by the Board of Appeal of the ECHA must take place⁷⁴.

Despite that, authorisation process has, to some extent, a decision-making process that is slightly opaquer, since where a substance of very high concern is at stake, the decision concerning the authorisation involves the Commission, acting on the basis of a comitology procedure⁷⁵.

⁷⁴ Cf. A. Volpato, E. Mullier, *The Board of Appeal of the European Chemicals Agency at a Crossroads*, in *Boards of Appeal of EU Agencies*, cit. at 43, 85-103.

⁷⁵ In this case, the reluctance of the EU institutions to confer authorisation powers on ECHA should probably be linked to the *Meroni* doctrine, and the

The registration procedure requires the producer or importers to provide data on the substance, to use them in order to assess the risk related to this substance and to suggest those risk-management tools which they consider appropriate. They thus must submit a dossier containing all this information to ECHA (Article 20). The Agency must undertake a completeness check usually within three weeks of the submission date, but a longer deadline is allowed for registrations of phase-in substances. The Agency then must notify the competent authority of the Member State where the manufacturer or importer are based within a time limit of 30 days from the submission date that the registration dossier together with other information are made available in the ECHA database. If from the Agency there is no indication to the contrary within three weeks of the submission date, the registrant may start or continue the manufacture or import of the substance.

The registration is followed by an evaluation process which could lead to the decision of ECHA, together with the Member State Committee, to include a given substance in the EU rolling action plan (Article 44) relying on any clue of risks for human health or the environment. When a registration set out to do further tests to have more specific information related to possible threats to human health or the environment, the Agency takes a decision upon the testing proposal according to the procedure laid down by Article 50 and 51.

A draft decision could be released by the Agency - in the event the process ended with a simple evaluation of the dossier concerning the substance - or by the competent authority of a Member State - when a full evaluation of the substance has been carried out. Therefore, ECHA must notify any draft decision to the registrant who has 30 days to submit comments to the Agency. If the draft decision was issued by the competent authority of the

willingness not to delegate tasks demanding the exercise of wide discretionary powers, and therefore implying political evaluations, to bodies falling outside either any kind of democratic legitimation or other institutional control mechanisms; see Case 9/56, *Meroni v High Authority*, ECLI:EU:C:1958:7. Cf. M. Simoncini, *Administrative Integration beyond the Non-Delegation Doctrine*, 2018, 29-31. Anyway, regulating procedures *ex ante* and making room for participation and other safeguards in the procedure might, to some extent, counterbalance such reluctance.

Member State to evaluate the substance, ECHA must inform them, since in that case the authority, instead of the Agency, is responsible for taking any comments into account and possibly amending the draft decision. Moreover, in both cases, the draft decision, together with the comments of the registrant, must be circulated among the competent authorities of the Member States which can propose amendments within 30 days.

A revised draft decision is therefore to be referred to the Member State Committee within 15 days. Any proposals for amendment have also to be communicated to the registrants allowing them to comment within 30 days, and the Member State Committee shall take any comment received into account. If, within 60 days from the referral, the Member State Committee reaches a unanimous agreement on the draft decision, the Agency must take the decision accordingly, otherwise the procedure under Article 133,3 applies.

The authorisation only concerns the placing on the market and use of those substances which have been labelled “of very high concern” - following an identification procedure - with the aim of keeping them under control and progressively replacing them with alternatives considered more suitable. According to Article 60, in these cases the authority responsible for granting their placing on the market is the Commission and the proceeding applies only if the risks linked to their use can be kept under control, or their use is needed for socio-economic reasons and no alternatives are available. However, before the file is sent to the Commission, the Committees for Risk Assessment and Socio-Economic Analysis of the Agency must give their draft opinions. The deadline set by Article 64,1 is ten months from the date of receipt of the application; afterwards the draft opinion is sent to the applicant who may provide, within one month, a written notice that they wish to comment, and they have one more month to send their written argumentation to the Agency.

Here, again, the Committees ought to take into consideration the comments and have two months to adopt their final opinion which, within a further 15 days the Agency shall send to the Commission, the applicant and the Member States, with written argumentation. The decision is to be taken by the Commission, which shall prepare a draft authorisation within three months of receipt of the opinions from the Agency. After that and assisted by a committee within three more months, as set

out by Article 133, 3, the final decision is adopted according to the regulatory procedure laid down by Council Decision no. 1999/468/EC⁷⁶.

Finally, when a substance already on the market poses a risk to human health or the environment, the Commission may ask ECHA – or a Member State acting on its own – to prepare a dossier. An assessment of the risks is therefore laid down by those provisions concerning the restriction of substances which presents a risk needing to be addressed. Their aim is to make those substances subject to a total or partial ban or to other sorts of restrictions. Within 12 months of the receipt of the request from the Commission, the Agency or a Member State may suggest restrictions and the specific procedure here begins involving the Committee for Risk Assessment and the Committee for Socio-Economic Analysis.

At first, they must check whether the dossier submitted conforms to the requirements and, if not, ask the Member State or Agency to supply the missing information within 60 days. After that, the Committees for Risk Assessment and Socio-Economic Analysis shall formulate their opinions as to whether the suggested restrictions are appropriate, considering both the dossier prepared either by the Agency or the Member State and the views of the interested parties submitted during a six-month mandatory public consultation. The opinions are submitted by the Agency to the Commission which has three months to prepare a draft amendment to Annex XVII of the regulation, concerning restrictions, to be adopted by the Commission with the help of the Committees according to the regulatory procedure.

A decision taken according to REACH has been challenged in case T-134/13⁷⁷, due to an alleged infringement of the right of defence claimed by the two complainants, *Polynt and Sitre*, respectively a manufacturer and an industrial user of a substance called HHPA – alleged to be a respiratory sensitiser. The applicants challenged the decision contesting the appropriateness of the kind of procedure applied to their case, also invoking the different degree of procedural rights acknowledged to the parties when an authorisation instead of an evaluation proceeding is

⁷⁶ Article 5 of Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

⁷⁷ T-134/13 *Polynt and Sitre v ECHA*, ECLI:EU:T:2015:254, para. 93 ff.

used. They contested the choice taken by ECHA, following to the submission of a dossier prepared by the Kingdom of Netherlands, to label HHPA as a substance “of very high concern”, according to an identification decision, possibly leading to listing HHPA among the substances subject to authorisation.

The applicants claimed, among other things, that the procedure followed was not the most appropriate one. An assessment under an evaluation procedure, compared to the authorisation procedure, would have allowed them to discuss the preliminary outcomes and provide relevant scientific data to the deciding authorities. The General Court rejected the plea of an infringement of the right of the defence underlining the different nature and purpose of an identification procedure applied – according to Article 59 – within an authorisation proceeding and that of an evaluation. Moreover, according to the judges, the intention of the legislator was precisely not to make the identification procedure carried out under Title VII of the regulation subject to the evaluation procedure ruled in its Title VI. Therefore, the judges concluded that “[b]y identifying HHPA on the basis of Article 57(f) of Regulation No 1907/2006, without first assessing it in the context of an evaluation procedure, the ECHA accordingly did not infringe the applicants’ right of defence”⁷⁸. Besides no manifest error of assessment took place according to the GC: all comments submitted by the applicants were properly taken into consideration during the identification procedure, since the authority had provided a response to each of them.

This case shows how hard it might be for stakeholders concerned by an agency decision to challenge the appropriateness of proceedings applied to them, and to have consequently different procedural guarantees to rely on. Especially when different proceedings would be equally suitable to achieve a given policy goal and highly complex scientific and technical facts need to be assessed, the discretionary power of the deciding authorities ends up prevailing. The latter is not only true relating to the wider or narrower extent of the judicial scrutiny into the challenged decision but can also prove to be true as regards the procedural pattern applied.

⁷⁸ *Ibid*, para. 101.

8. Indirect administration and fundamental rights

In this final paragraph the analysis shifts to the highly sensitive issue of migration law, where only indirect administration is applied. Nevertheless, procedural problems have emerged in the last few years during trials before the EU courts which appear to be quite close to those affecting direct and composite procedures. Unlike all the pieces of legislation considered thus far, the most interesting aspect of these procedures is that – affecting indirect administration – they involve the principle of the procedural autonomy of Member States. This gives the chance to see whether and how the Union can effectively assure common procedural standards to administrative tasks falling within its competences, despite them being implemented exclusively at national level. Some unpredictable steps forward have been made thanks to procedures concerning the acknowledgement of international protection status which have been under scrutiny⁷⁹ in the past, in the context of the migrant crisis.

A truly ground-breaking judgment was the one delivered by the Court of Justice in Case C-604/12⁸⁰ related to the

⁷⁹ In C-277/11, *M.M. v Minister for Justice, Equality and Law Reform* (Ireland), ECLI:EU:C:2012:744, the ECJ decided that a right to be heard must be guaranteed to an applicant for subsidiary protection even though the applicable legislation does not expressly provide for such a procedural guarantee. Cf. C. Hruschka, *The (reformed) Dublin III regulation – a tool for enhanced effectiveness*, 15 ERA Forum 479 (2014), where that case-law is linked to the new applicable Article 5 of the Dublin III regulation providing for the right to be heard in the form of a personal interview. See Article 5, regulation (EU) No 604/203 of 26 June 2013 establishing the criteria and mechanisms for determining the Member State responsible for examining an application for international protection lodged in one of the Member States by a third-country national or a stateless person, but also Article 14 and ff. of directive 2013/32/EU of 26 June 2013 on common procedures for granting and withdrawing international protection.

⁸⁰ C-604/12, *H.N. v Minister for Justice, Equality and Law Reform* (Ireland), EU:C:2014:302. S. Bogojević, X. Groussot, M. Medzmariashvili, *Adequate Legal Protection and Good Administration in EU Asylum Procedures: H.N. And Beyond*, 52 Common Mkt. L. Rev 1635-60 (2015). The Irish Supreme Court raised the question of whether a Member State is allowed to lay down in its national legislation that an application for subsidiary protection status can be considered only after the applicant has applied for and been refused refugee status. Since Ireland decided for two separate procedures, one following the other, to examine asylum and subsidiary protection applications, Directive 2005/85 would not have applied to the former. Cf. Articles 12 and 13(3) of Council

procedural rights concerning Council Directive 2004/83/EC⁸¹. In this case the court applied the principle of effectiveness⁸² in view of limiting national procedural autonomy. However, in doing so, it relied on “good administration” as a general principle and fundamental subjective right enshrined in Article 41 of the EU Charter of Fundamental Rights in a proceeding concerning the recognition of refugee status or, alternatively, subsidiary protection⁸³. In its reasoning to explain the decision, the court not only recalled that a right to be heard is inherent as a fundamental principle of EU law – that is, the right of the defence – but it is now affirmed also in Article 41 of the CFR, which lays down the right to good administration, a provision considered by the ECJ to be of general application⁸⁴.

directive 2005/85/EC of 1 December 2005 on minimum standards on procedures in Member States for granting and withdrawing refugee status.

⁸¹ Council directive 2004/83/EC of 29 April 2004 on minimum standards for the qualification and status of third-country nationals or stateless persons as refugees or as persons who otherwise need international protection and the content of the protection granted. This directive has been now repealed by Directive 2011/95/EU, of 13 December 2011 on standards for the qualification of third-country nationals or stateless persons as beneficiaries of international protection, for a uniform status for refugees or for persons eligible for subsidiary protection, and for the content of the protection granted, which further approximated the rights of persons who have been granted refugee status and those of persons with subsidiary protection status. Cf. on the latter H. Dörig, I. Kraft, H. Storey, H. Battjes, *Asylum Qualification Directive 2011/95/EU*, in K. Hailbronner, D. Thym (eds.), *EU Immigration and Asylum Law: a commentary* (2016), 1108-1283.

⁸² Cf. H. Hofmann, *European administration: nature and developments of a legal and political space*, in *Research Handbook on EU Administrative Law*, cit., 32 “[f]rom the ‘inside’, however, the system is held together by procedural law. In this, an administrative space is created in which joint creation of law and its implementation is a reality. Limitations on autonomy of Member States arise from the fact that, in the fields of Union policy, the substantive and procedural administrative law of Member States is to be applied within the framework of EU law. This is set by reference to three basic factors. First, the substantive and procedural law of Member States is applicable as such only in the absence of any explicit requirements in Union law [...]. Secondly, the application of national procedural rules in the implementation of Union law, [...] must be exercised in strict compliance with the principles of *equivalence* and *effectiveness*. Thirdly, in all areas of the ‘scope’ of EU law, Member States are subject to general principles of EU law and fundamental rights”.

⁸³ C-604/12, *H.N.*, paras. 49-50.

⁸⁴ Cf. C-277/11, *M.M.*, par. 83.

Although there were at that time no common rules determining what shall be the procedural standards to be followed by national administrations when examining an application for international protection, it was nevertheless made clear by the court that the Member States shall determine them ensuring that fundamental rights are observed and that EU provisions on subsidiary protection⁸⁵ are *fully effective*⁸⁶. Accepting the opinion of A.G. Bot, the ECJ understood this fully effective protection in such a way that national law needs to grant the chance of simultaneous applications for refugee status and subsidiary protection status and is required to consider such applications “within a reasonable period of time”⁸⁷.

Thanks to this judgment the ECJ gave an example on how to use Article 41 CFR to limit national procedural autonomy. The judgment would have led⁸⁸ to the creation of a *ius commune*, at least whenever a procedure involving fundamental human rights is concerned⁸⁹, such as that applying to a third-country national with a view to granting them international protection status, according to international treaty law⁹⁰. Therefore, reference to the principle of effectiveness, coupled with that to good administration, has led to an expansion⁹¹ of the normative applicability of EU procedural rights well beyond the fields of direct or joint administrative proceedings, overturning settled case law⁹².

⁸⁵ Cf. Article 78, par. 2 (a) and (b) TFUE.

⁸⁶ C-604/12, *H.N.*, paras. 41-42.

⁸⁷ *Ibidem.*, par. 45.

⁸⁸ S. Bogojević, X. Groussot, M. Medzmariashvili, *Adequate Legal Protection and Good Administration in EU Asylum Procedures: H.N. And Beyond*, 52 *Common Mkt. L. Rev.* 1659 (2015); see also J. Vedsted, Hansen, *Asylum procedures: seeking coherence within disparate standards*, in E. Tsourdi, P. De Bruycker (eds.), *Research Handbook on EU Migration and Asylum Law* (2022), 243-262.

⁸⁹ Cf. Directive 2004/83/UE at pt. 14 of the preamble, and now Directive 2011/95/UE, at pt. 21 of the preamble.

⁹⁰ The Geneva Convention of 28 July 1951 relating to the Status of Refugees and its New York Protocol relating to the Status of Refugees of 31 January 1967, affirming the principle of non-refoulement, and ensuring that nobody is sent back to persecution.

⁹¹ M.P. Chiti, *Diritto amministrativo europeo* (1999), 145.

⁹² On the opposite side, see Case C-482/10, *Cicala*, 21 December 2011 ECLI:EU:C:2011:868, concerning a purely internal situation, *i.e.*, a pension treatment. This circumstance explains why the ECJ answered that, though

However, the same reasoning has not found application in judgments relating to a different kind of indirect procedure – which is an example of an administrative decision adversely affecting the individual – even though it falls within migration policies like the previous one. The applicable legislation is Directive 2008/115/UE⁹³ concerning the decisions of Member States to return illegally resident third-country nationals⁹⁴. The directive sets some procedural safeguards in its Chapter III, but it does not specify whether, and under what conditions, observance of the right of the third-country nationals to be heard must be ensured when the return policy is applied.

Since French law implementing Directive 2008/115/UE makes no reference to the conditions under which a foreign country national must be heard before a returning decision is issued in their regard, the referring court⁹⁵ asked whether national authorities should put third-country nationals in a position to be heard by virtue of Article 41, para. 2 (a) CFR⁹⁶. The court, deviating from the opinion of the advocate-general⁹⁷, answered that an applicant for a resident's permit cannot derive any right to be heard from the Charter.

The court acknowledged the latter as a general principle of EU law which Member States ought to guarantee according to the

Article 1 of Law No 241/1990 contains a reference to principles deriving from EU law, that internal situation could not be treated as those falling within EU law would be. Cf. para. 29 of the judgment. In *H.N.*, contrary to *Cicala*, the application of Article 41 CFR to a national procedure seems to rely on the fact that it involves a situation falling within EU law. Cf. also C-617/10, *Åklagaren v Åkerberg Fransson*, paras. 19-21, ECLI:EU:C:2013:105 and C-390/12, *Pfleger and Others*, para. 34, ECLI:EU:C:2014:281.

⁹³ Directive 2008/115/UE of the European Parliament and Council of 16 December 2008 on common standards and procedures in Member States for returning illegally resident third-country nationals.

⁹⁴ C-166/13, *Mukarubega*, ECLI:EU:C:2014:2336 and C-249/13, *Boudjlida*, ECLI:EU:C:2014:2431.

⁹⁵ C-249/13, *Boudjlida*, para. 33-34.

⁹⁶ Relying on the case law of the ECJ in C-277/11, *M.M.*

⁹⁷ AG Wathelet stated at para. 47 of his opinion: “[i]t seems to me neither consistent nor in accordance with the case law of the Court for the wording of Article 41 of the Charter to allow the introduction of an exception to the rule laid down in Article 51 thereof enabling the Member States not to apply an article of the Charter, even when they are implementing Union law. I am therefore clearly in favour of the applicability of Article 41 of the Charter to the Member States when they are implementing Union law”. ECLI:EU:C:2014:2032.

principles of equivalence and effectiveness. But the judges also recalled that this general principle cannot be considered an unfettered prerogative and may be restricted, under certain circumstances, in view of its balancing with the need to implement an effective return policy. Thus, considering the right to be heard as a general principle of EU law, rather than a subjective procedural right enshrined in primary law, the ECJ succeeded in giving room to a more yielding interpretation of procedural requirements within national legislation. This condition, nevertheless, has a side effect. It gives more power to the EU courts which would exercise it on a case-by-case basis, undermining the predictability of the results, and boosting their judicial activism by adding even more relativism.

9. Concluding remarks

Considering the results of the inquiry, several points of weakness emerge from the absence of a general framework of rules concerning administrative procedures in the EU legal order. First, not all the institutions have the same understanding of how to apply the principles of good administration to an administrative procedure. Such an acknowledgment can be even more striking when making a comparison between procedures related to integrated administration – where committees and EU regulatory agencies ought to be seen as key supranational components – and indirect administration, leaving aside those cases where fundamental human rights are implied in the procedure because peculiar considerations seem to apply there. At a very first glance, these differences could be seen to add some flexibility for the benefit of the decision-making authorities, but they are usually detrimental to the parties which can hardly foresee and replicate the same behaviour moving from one sector-specific legislation to another⁹⁸. Moreover, this being the case, there is far more space for judicial activism in reviewing decision-making, adding some uncertainty to the very outcome of a given

⁹⁸ Just to exemplify, there is still an underestimated difference between public access and access of interested persons in individual case decision-making; likewise, “reasonable time” in decision-making is still a difficult concept to define. Cf. T-347/03 *Branco v Commission*, ECLI:EU:T:2005:265, para. 114.

proceeding⁹⁹.

On the one hand, relying only on due process principles or Article 41 CFR could strengthen the discretionary powers of the institutional player but, on the other, such a choice could also prove to be inconsistent with the principle of proportionality or effectiveness, nor be reviewable as such, due to the extensive degree of technical discretion. For this reason, the role of the European Ombudsmen has been so important thus far¹⁰⁰, because they have the duty to detect whether administrative acts, even though lawful, could be disproportionate, burdensome, unfair, or unreasonable: the use of discretionary power is the core target of the EU Ombudsmen's control, and their intervention is sometimes much more effective than a judicial one.

Once the consequences of this gap in positive legislation became apparent, the issue concerning how the situation could improve thanks to codification ought to be tackled. First, officials could be obliged to adopt a sound conduct, to behave properly, according to minimum standards set by the general rules on administrative procedure in every case, even where no specific provisions apply to a given situation. This could also lead to a clearer definition of what is a standard procedure, allowing comparisons and self-improvement within institutions which should be called on to share their best practices.

Moreover, even though a codification could be considered a hazardous endeavour because of the fear of the public authorities of losing their discretionary powers, on the other hand, it would have the powerful consequence of increasing people's feeling of being treated fairly thanks to uniform procedural standards laid down in a single piece of legislation working as a general framework. This could foster a culture of openness, efficiency and accessibility in the EU administration to an extent that is not even foreseeable as long as uncertainties and scattered rules governing EU administrative activities persist, as this paper has tried to demonstrate.

⁹⁹ For an opposite conclusion, prizing the active role of judges, cf. C. Eckes, J. Mendes, *The Right to Be Heard in Composite Administrative Procedures*, cit. at 2, 670.

¹⁰⁰ M. Inglese, *The external projection of EU's agencies. An emphasis on the Ombudsman's role*, TARN working paper No. 13 (2017), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3048222.

To some extent, a general act on administrative procedure could be one *tessera* in the more complex system of “accountability regimes”¹⁰¹. It would certainly constrain the decision-making public authorities to take all the steps needed to reach the most considered decisions, thanks to a proper evaluation and balancing of all the interests involved, leading to an overall improvement in bureaucratic effectiveness – implying cost savings – and accountability from the point of view of citizens.

As already mentioned, the position of the Commission is that any benefit arising from a codification would not outweigh the costs related to a revision of most existing legislation¹⁰². However, an APA would lead to several hidden cost savings insofar as future rule-makers or administrations will simply rely on the general provisions, concentrating their efforts in laying down those procedural details concerning sector-specific needs. In any case, it is self-explanatory that in those cases, sector-specific procedural rules should grant the same or higher levels of guarantee to citizens, even though the outline of the procedure would be – to some extent – modified.

However, this kind of reasoning is certainly true whenever facing a procedure that can be labelled as adjudicative – or first-generation procedures¹⁰³ – according to classical standards. But the picture becomes even more puzzling dealing with third-generation procedures, the most common ones in the EU landscape. As a reference point could be taken one of the many proceedings involving agencies which are becoming one of the main players in the EU administration, the proceedings of which acquire the greatest relevance considering that they are meant to overcome the issue of democratic accountability with a shift to a procedural one.

Agencies are often asked to provide for risk-assessment or risk-management decisions to be included within a rule-making procedure of the Commission, involving committees.

¹⁰¹ E. Chiti, *Is EU Administrative Law Failing in Some of Its Crucial Tasks?*, 22 Eur. L. J. 590 (2016).

¹⁰² Cf. the answer of the Vice-President of the Commission, Jyrki Katainen, during a debate on oral interpellation held at the European Parliament in Strasbourg 8 June 2016, CRE 08/06/2016 - 26.

¹⁰³ According to J. Barnes, *Towards a third generation of administrative procedure*, cit. at 40.

Here, the boundaries between legislation and adjudication are so blurred and proceedings are so complex and tailored¹⁰⁴ that those affected by the final outcome would obviously benefit from a standard-setting APA to look at, standing beside sector-specific provisions. From this point of view, the efforts made by ReNEUAL with its Model Code seems to better address the procedural entanglements within the EU administrative panorama than the proposal of the European Parliament. The reason is that, as already mentioned, the former includes in the project provisions concerning not only adjudication but also administrative rule-making, mutual assistance and administrative information management among other things, while the latter only focus on individual decision-making procedures. Despite that, the proposal contained in the resolution of the European Parliament – with its minimalist attitude – shows a more realistic and strategic approach considering the clear hesitancy of the Commission on this issue.

¹⁰⁴ Cf. U. Stelkens, *The European Administrative Space – From integration to implosion: A return journey?*, available at <https://europeancommonwealth.org/2017/02/17/stelkens-the-european-administrative-space-from-integration-to-implosion-a-return-journey/>.