

# Judicial Review of the Acts of EU Agencies

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# **Judicial Review of the Acts of EU Agencies: Discretion Escaping Scrutiny?**

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## **Abstract**

The creation and empowerment of European Union (EU) agencies constitutes one of the most momentous developments of the EU composite administration. In the last decades, the delegation of powers to EU agencies grew exponentially both in quantitative and qualitative terms. As a result of this evolution and of the more permissive position of the Court of Justice of the EU in the *Short selling* judgment, EU agencies today are called upon to make relevant political, economic and social choices even in highly sensitive and contentious domains. The possibility to challenge their acts has been finally sanctioned in primary law. The exercise of their powers, however, is subject only to a limited scrutiny by the Court, which has recognized broad discretion to these bodies in carrying out complex and technical assessments. Analysing the approach of the Court to the review of European Chemical Agency's (ECHA) discretion, this paper reflects upon its effectiveness and its implications for the accountability and legitimacy of agencies within the EU institutional framework.

## 1. Introduction

The creation and empowerment of European Union (EU) agencies undeniably constitutes one of the most momentous developments of the EU composite administration. These permanent bodies with separate legal personality under EU public law, set up by the institutions through secondary legislation,<sup>1</sup> represent “a specific institutional arrangement” which stands out within the EU institutional panorama.<sup>2</sup> Since the 1990s, agencification has progressively grown both in quantitative and qualitative terms. The growing involvement of the EU in deeply complex policy domains increasingly required forms of technical and scientific expertise from the rule-maker, which the EU institutions generally lacked.<sup>3</sup> Often established as an *ad hoc* reaction to transnational crises, the EU agencies also represented a credible solution for the need to provide an effective implementation of EU law at the centralised level when the Member States could not accept a further empowerment of the Commission.<sup>4</sup>

Thus, from the first agencies in the 1970s, which were entrusted with merely informational tasks, the number of decentralised agencies has exponentially increased to more than 30 bodies, which are significantly diverse in their functions, structure and in the powers conferred. Indeed, EU agencies not only carry out preparatory work for the decision-making of EU institutions, but they can also adopt acts of individual or general application vis-à-vis third parties.<sup>5</sup> Although the conferral of far-reaching powers to EU agencies without an express legal basis in the Treaties and without clear constitutional boundaries initially raised relevant concerns of legitimacy,<sup>6</sup> this empowerment was unequivocally sanctioned by the Court in the *Short Selling* judgment under certain conditions.<sup>7</sup> Thus,

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<sup>1</sup> According to the definition of EU agencies provided by Merijn Chamon, *EU Agencies. Legal and Political Limits to the Transformation of the EU Administration* (Oxford University Press 2016), 9. Compare this definition with the one proposed by Madalina Busuioc, *European Agencies: Law and Practices of Accountability*, (Oxford University Press 2013), 21.

<sup>2</sup> Edoardo Chiti, ‘European Agencies’ Rulemaking: Powers, Procedures and Assessment’ [2013] 19 *European Law Journal* 93, 94.

<sup>3</sup> Madalina Busuioc, *op. cit.* (2013), 25.

<sup>4</sup> See Renaud Dehousse, ‘Regulation by Networks in the European Community: The Role of European Agencies’ [1997] 4 *Journal of European Public Policy* 246.

<sup>5</sup> They are accordingly distinguished between ‘pre-decision-making’ agencies (or ‘*de facto* decision-making’ agencies) and genuine ‘decision-making’ agencies. See, *inter alia*, the taxonomy in Herwig C. H. Hofmann and Alessandro Morini, ‘Constitutional Aspects of the Pluralisation of the EU Executive through “Agencification”’ [2012] 37 *European Law Review* 419.

<sup>6</sup> *Inter alia*, Damien Gerardin, ‘The Development of European Regulatory Agencies: Lessons from the American Experience’ in Damien Girardin, Rodolphe Munoz and Nicolas Petit (eds), *Regulation through agencies in the EU: a new paradigm of European governance* (Edward Elgar 2005), 231; Ellen Vos, ‘Reforming the European Commission: What Role to Play for EU Agencies?’ [2000] 37 *Common Market Law Review* 1113.

<sup>7</sup> See Case C-270/12, *UK v Council of the European Union and European Parliament (Short Selling)* [2014] EU:C:2014:18.

in the shadow of primary law, EU agencies today are called upon to make relevant political, economic and social choices even in highly sensitive and contentious domains.<sup>8</sup>

The exercise of these powers, however, requires them to be accountable, in particular judicially accountable, to comply with the tenets of democracy and the rule of law on which the EU is based.<sup>9</sup> As emphasised by the Court in *Les Verts*, the EU “is a Community based on the rule of law, inasmuch as neither its Member States nor its institutions can avoid a review of the question whether the measures adopted by them are in conformity with the basic constitutional charter, the Treaty.”<sup>10</sup> A full judicial review of the exercise of their activities, however, is arguably faced with significant hurdles given, on the one hand, by the late recognition of agencies in primary law and, on the other hand, by the complexity of the assessments carried out by these bodies. Therefore, this paper will analyse the judicial review of the exercise of EU agencies’ powers, examining, firstly, the possibility of challenging agencies’ acts through an action for annulment according to Article 263 TFEU in its historical evolution. Secondly, it will focus on the intensity of the scrutiny exercised by the Court on EU agencies’ discretion, adopting in particular as a case study the review of the acts of the European Chemical Agency (ECHA). Thirdly, the implications of a limited judicial review from a constitutional perspective will be considered. Although based on preliminary results, some conclusions will be drawn.

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<sup>8</sup> For a recent overview of this phenomenon, see the study carried out by Ellen Vos on behalf of the European Parliamentary Research Service, ‘EU Agencies, Common Approach and Parliamentary Scrutiny’, <http://www.europarl.europa.eu> (last accessed on 12.01.2019).

<sup>9</sup> Article 2 TEU; Case 294/83, *Les Verts v Parliament* [1986] EU:C:1986:166, para 23.

<sup>10</sup> Case 294/83, *Les Verts*, para 23.

## 2. The Reviewability of the Acts of EU Agencies

Article 263(1) TFEU sets forth that the Court can review the legality of “acts of bodies, offices or agencies of the Union intended to produce legal effects vis-à-vis third parties”. Therefore, the possibility to challenge the acts adopted by agencies is now expressly provided in primary law, sanctioning the passive *locus standi* of EU agencies in actions for annulment. However, the mention of EU agencies in Article 263 TFEU was a significant innovation of the Lisbon Treaty, which follows a long and erratic evolution of the case law on this point.<sup>11</sup>

### 2.1. The Evolution of the Case Law on the Annulment of Agencies’ Acts

Before the introduction of the mention of EU agencies in Article 263 TFEU, the jurisdiction over the acts of EU agencies was not immediately accepted by the Court. With the exception of the plea of illegality,<sup>12</sup> the Court for a long time adopted a formalistic interpretation of the treaty provisions concerning judicial review, excluding the possibility to challenge agencies’ acts.<sup>13</sup>

Nevertheless, certain founding regulations of the agencies contained a provision which conferred jurisdiction on the Court for the judicial review of their acts.<sup>14</sup> These provisions, however, constituted an exception. In any case, the regulations generally limited the jurisdiction of the Court to cases concerning the contractual and non-contractual liability of these bodies and access to documents.<sup>15</sup> These provisions concerning jurisdiction have been interpreted restrictively by the Court, not allowing the judicial review of other acts than those expressly mentioned.<sup>16</sup> Therefore, emphasising that the agencies were not among the institutions listed in the relevant treaty provisions on jurisdiction, the Court used to reject the applications brought against acts with legal effects which

<sup>11</sup> See Carlo Tovo, *Le agenzie decentrate dell’Unione europea* (Editoriale Scientifica 2016), 342-361.

<sup>12</sup> See Case T-120/99, *Kik v UAMI* [2001] EU:T:2001:189, para 21.

<sup>13</sup> Carlo Tovo, *op. cit.* (2016), 343.

<sup>14</sup> See Article 22 of Regulation (EC) No. 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), OJ L 376, 27.12.2006, p. 1–13, p. 1–8: “The Court of Justice shall have jurisdiction in actions brought against the Centre under Article 230 of the Treaty”; Article 27(3) of Council Regulation (EC) No. 168/2007 of 15 February 2007 establishing a European Union Agency for Fundamental Rights, OJ L 53, 22.2.2007, p. 1–14: “The Court of Justice shall have jurisdiction in actions brought against the Agency under the conditions provided for in Articles 230 and 232 of the Treaty.” For a criticism of this practice, which creates legal uncertainty, see Merijn Chamon, *op. cit.* (2016), p. 337.

<sup>15</sup> All the basic regulations contain a provision of this kind: “1. The contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority. 2. In the case of non-contractual liability, the Authority shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage.” See, for instance, Article 47 of EFSA Regulation.

<sup>16</sup> See Case T-411/06, *Solgema v EAR* [2008] EU:T:2008:419, para 34.

affected third parties on grounds of inadmissibility.<sup>17</sup> Although in the specific cases other judicial remedies were open to the applicants,<sup>18</sup> the inadmissibility of a direct challenge of these acts appeared as a remarkable lacuna in the jurisdictional system of EU law.<sup>19</sup>

Such a lacuna, actually, was attenuated by the existence of a sort of “administrative appeal” to the Commission<sup>20</sup> and by the application of the *SNUPAT* case law to EU agencies.<sup>21</sup> Thus, on the one hand, the basic regulations contained a mechanism which allowed for a referral of a contested measure of the agency to the Commission, which was required to review the legality of the measure. The subsequent decision of the Commission on the matter, then, constituted a challengeable act subject to the jurisdiction of the Court, thus providing an indirect means for judicial protection.<sup>22</sup> On the other hand, the Court applied the principle enshrined in *SNUPAT* to EU agencies, according to which the decisions adopted by auxiliary organs or agencies were to be attributed to the Commission. Indeed, considering that such bodies were created and derived their powers from the Commission, their acts were eventually imputable to the Commission.<sup>23</sup> Therefore, it was possible for the applicant to challenge the decision of an agency, in particular of the European Medicines Agency (EMA), by lodging an application against the Commission<sup>24</sup> - but this was possible against the Commission only.<sup>25</sup>

However, the extension of this case law to EU agencies was far from being unproblematic. Firstly, it represented an exception to the consolidated principle that the action for annulment needs to be directed against the author of the act concerned, constituting the outcome of the decision-making power of that authority.<sup>26</sup> Secondly, while the argument that the set up and delegation of powers

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<sup>17</sup> Case T-148/97, *Keeling v OHIM* [1998] EU:T:1998:114; Case C-160/03, *Spain v Eurojust* [2005] EU:C:2005:168, paras. 36-37.

<sup>18</sup> As remarked in Case T-411/06, *Solgema*, para 45.

<sup>19</sup> This problematic aspect was also noted in European Commission, Communication - The operating framework for the European Regulatory Agencies, COM(2002) 718, last paragraph.

<sup>20</sup> As named by Richard H. Lauwaars, ‘Auxiliary Organs and Agencies in the EEC’ [1979] 16 *Common Market Law Review*, 380.

<sup>21</sup> See Joined Cases 32-33/58, *SNUPAT v High Authority* [1959] EU:C:1959:18, 137-138. The case concerned an action for the annulment of a decision of the Imported Ferrous Scrap Equalization Fund, which was considered admissible by the Court because the Fund was set up and held its powers from the High Authority. Therefore, its decisions were to be equated to the decisions of the High Authority.

<sup>22</sup> See Carlo Tovo, *op. cit.* (2016), p. 343.

<sup>23</sup> Joined Cases 32-33/58, *SNUPAT v High Authority*, EU:C:1959:18, pp. 137-138.

<sup>24</sup> Case T-123/00, *Thomae v Commission*, EU:T:2002:307, para 97.

<sup>25</sup> Case T-133/03, *Schering-Plough v Commission and EMEA*, EU:T:2007:365, para 23.

<sup>26</sup> *Inter alia*, Case C-201/89, *Le Pen and Front National* [1990] EU:C:1990:133, para 14; Case C-97/91, *Oleificio Borelli v Commission* [1992] EU:C:1992:491, paras 9-10; Case T-45/06, *Reliance Industries v Commission and Council* [2008] EU:T:2008:398, paras 50-51. *Contra*, another exception to the principle can be found in Case T-49/04, *Hassan v Council*

derived from the Commission was understandable in relation to the “Brussels agencies”<sup>27</sup> or the executive agencies, the decentralised agencies are created and empowered by the legislator, i.e. the Council, or the Council and Parliament.<sup>28</sup> Therefore, attributing the agency’s powers to the Commission constitutes a misunderstanding of the chain of delegation and of the institutional transformation occurred within the agencification phenomenon. Thirdly, the resulting rejection of any action brought against the EU agencies, on the ground that the Commission was the correct defendant,<sup>29</sup> represented a distortion of the *SNUPAT* principle, which was originally put forward with the intention of expanding the jurisdiction of the Court and the judicial protection of individuals.<sup>30</sup> Finally, both these mechanisms - the extension of the *SNUPAT* case law and the provision of an administrative appeal to the Commission - appeared at odds with the institutional independence of EU agencies, which operate at arm’s length from the authority of the Commission.<sup>31</sup>

## 2.2. *The Solgema Case and the Lisbon Treaty*

In light of these considerations, a *revirement* of the case law on the judicial review of the agencies’ acts was particularly desirable.<sup>32</sup> The Court took this step only in 2008, just before the entry into force of the Lisbon Treaty.

The *Sogelma* case, which concerned the annulment of decisions of the European Agency for Reconstruction (EAR) relating to a tender procedure, represented the turning point in the position of the Court on this matter.<sup>33</sup> Ruling on the admissibility of the action, the Court started by recalling

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*and Commission* [2006] EU:T:2006:201, para 59. See Grainne De Burca, “The Institutional Development of EU: A Constitutional Analysis” in Paul Craig and Grainne De Burca (eds), *The Evolution of EU Law* (Oxford University Press 1999), 76.

<sup>27</sup> Namely, the “Joint Bureau of Scrap Consumers” and the “Imported Ferrous Scrap Equalisation Fund”, which were the object of the case 9/56, *Meroni*, EU:C:1958:7.

<sup>28</sup> On the break in continuity among the two kind of bodies, see Merijn Chamon, “EU Agencies: Does the Meroni Doctrine Make Sense?” [2010] *Maastricht Journal of European and Comparative Law* 281; Merijn Chamon, ‘EU Agencies Between Meroni and Romano or the Devil and the Deep Blue Sea’[2011] 48 *Common Market Law Review* 1055; Carlo Tovo, *op. cit.* (2016), 348.

<sup>29</sup> See Case T-133/03, *Schering-Plough v Commission and EMEA*, EU:T:2007:365, para 23.

<sup>30</sup> Paul Craig and Grainne De Burca, *EU Law. Text, Cases and Materials* (5th edn, Oxford University Press 2011), p. 493; Carlo Tovo, *op. cit.* (2016), 348.

<sup>31</sup> Carlo Tovo, *op. cit.* (2016), 348.

<sup>32</sup> The extension of the *Les Verts* case law to EU agencies was particularly supported by LENAERTS Koen, ‘Regulating the Regulatory Process: Delegation of Powers in the European Community’ [1993] 18 *European Law Review*, 45-46. See also Case C-15/00, *Commission v EIB* [2003] EU:C:2003:396.

<sup>33</sup> Case T-411/06, *Sogelma v EAR* [2008] EU:T:2008:419. For a comment, see Elsa Bernard, ‘Recours contre les actes des agences’ [2008] *Europe*, 14-16; Elisabetta Piselli, ‘Minimum Selection Criteria and their Application during the Evaluation Process: Sogelma Srl v European Agency for Reconstruction (EAR)’ [2009] *Public Procurement Law Review* 83; Georges

the principle enshrined in *Les Verts*.<sup>34</sup> Since the EU is “a community based on the rule of law”, the Treaties must be interpreted as permitting the Court of Justice to review the legality of measures adopted by its institutions. Accordingly, there is, in the general scheme of primary law, the possibility “to make a direct action available against all measures adopted by the institutions which are intended to have legal effects”.<sup>35</sup> Although not expressly established in primary law, it derives from that case that “any act of a Community body intended to produce legal effects vis-à-vis third parties must be open to judicial review”, including acts of EU agencies.<sup>36</sup> In the absence of such a possibility, there would be an unacceptable “legal vacuum” in the judicial review of EU acts.<sup>37</sup>

The Court, thus, recognised an important continuity between the acts adopted by the institutions, in particular the Parliament in *Les Verts*, and those of the agencies, and could not accept that a delegation of powers from an institution to another body would deprive the applicants of judicial protection. Moreover, the reasoning of the Court was justified by the fact that, different from the previous cases, no other judicial remedy was available to the applicant.<sup>38</sup> In this sense, the case has been read as a logical development of the previous case law, which, interpreted *a contrario*, would have paved the way for a recognition of direct action against agencies’ acts where no other remedies were available.<sup>39</sup>

However, more than in the distinction of this case from the previous cases, this *revirement* of the Court should be considered in the light of the changing institutional context. Indeed, the Lisbon Treaty was already signed and about to enter into force, definitively opening the way for the direct judicial review of agencies’ acts.<sup>40</sup>

### 2.3. *The Last Lacuna: The Third Pillar Agencies*

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Vandersanden, ‘Arrêt "Sogelma": l'annulation d'actes adoptés par des organes établis sur la base du droit dérivé’ [2008] *Journal de droit européen*, 297-298.

<sup>34</sup> Case 294/83, *Les Verts*, para 24. For an analysis, see Chapter 2, para 7.4. This case was cited already in the Opinion of Advocate General Poiares Maduro in Case C-160/03, *Spain v Eurojust* [2004] EU:C:2004:817, paras 15-21; and considered as crucial precedent before the case by Koen Lenaerts, ‘Regulating the Regulatory Process: Delegation of Powers in the European Community’ [1993] 18 *European Law Review*, 23; Edoardo Chiti, ‘An Important Part of the EU Institutional Machinery: Features, Problems and Perspectives of European Agencies’ [2009] 46 *Common Market Law Review*, p. 1420.<sup>35</sup> Case T-411/06, *Sogelma*, para 36.

<sup>35</sup> Case T-411/06, *Sogelma*, para 36.

<sup>36</sup> *Ibid*, para 37.

<sup>37</sup> *Ibid*, para 40.

<sup>38</sup> *Ibid*, paras. 41-43.

<sup>39</sup> See Renzo Rossolini, ‘La competenza del giudice comunitario per l'annullamento degli atti delle agenzie europee’ [2009] *Diritto comunitario e degli scambi internazionali*, 496; Carlo Tovo, *op. cit.* (2016), 351.

<sup>40</sup> See also Carlo Tovo, *op. cit.* (2016), 351.

Despite the improvements in the case law, a lacuna remained for certain agencies.<sup>41</sup> Indeed, Europol and Eurojust remained outside judicial scrutiny since they were part of the so-called Third Pillar, thus being subject to limited scrutiny of the Court.<sup>42</sup> In particular, the issue was raised in the *Spain v Eurojust* case, concerning the annulment of a call for application for the recruitment of temporary staff at the agency.<sup>43</sup> While the Advocate General took a strong position for the admissibility of the annulment by making an analogy with *Les Verts*,<sup>44</sup> the Court refused to take such an innovative step, steering clear from ruling on the matter.<sup>45</sup>

For these agencies, therefore, the Lisbon Treaty constituted a true ground-breaking innovation, which finally filled this “significant and salient treaty lacuna”.<sup>46</sup> With the abolition of the Pillar structure, also the agencies in the Area of Freedom Security and Justice are subject to the Court’s judicial review according to Article 263 TFEU.<sup>47</sup>

#### 2.4. *The Review of Acts Not Intended to Produce Legal Effects vis-à-vis Third Parties*

The expansion of the scope of the action for annulment in Article 263 TFEU to the agencies concerns the acts “intended to produce legal effects vis-à-vis third parties”. Therefore, the acts adopted by genuine decision-making agencies, which are delegated formal powers towards third parties, can be challenged before the Court of Justice, lodging the action directly against the agency as defendant. In fact, a relevant number of actions against these agencies, such as the European Union Intellectual Property Office (EUIPO) or the Community Plant Variety Office (CPVO), are now initiated every year in Luxembourg.<sup>48</sup>

However, such direct action appears precluded in relation to agencies which do not exercise genuine decision-making powers. Indeed, certain agencies are involved in the preparation of acts eventually adopted by other institutions, issuing opinions which constitute the basis for the final decisions (the

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<sup>41</sup> See Madalina Busuioc, *op.cit.*, 206.

<sup>42</sup> See Article 46 former TEU. For a criticism, see, *inter alia*, Steve Peers, ‘Salvation outside the Church: Judicial Protection in the Third Pillar after the *Pupino* and *Segi* Judgments’ [2007] 44 *Common Market Law Review* 885.

<sup>43</sup> Case C-160/03, *Spain v Eurojust* [2005] EU:C:2005:168.

<sup>44</sup> Opinion of Advocate General Poiares Maduro in Case C-160/03, *Spain v Eurojust* [2004] EU:C:2004:817, paras 20-21.

<sup>45</sup> Case C-160/03, *Spain v Eurojust*, para 41.

<sup>46</sup> Deirdre Curtin, *Executive Power of the European Union. Law, Practices and the Living Constitution* (Oxford University Press 2009), 162. However, on the qualifications of this opening in relation to the transitional period and to the decisions of the JSBs of Europol and Eurojust, see Madalina Busuioc, *op. cit.* (2013), 210.

<sup>47</sup> Paul Craig, *EU Administrative Law* (Oxford University Press 2012), 159.

<sup>48</sup> For instance, in 2017 almost 300 actions were brought before the General Court just against EUIPO.

so-called “pre-decision-making agencies”<sup>49</sup>), or they adopt soft law measures such as recommendations, guidelines and other informal documents.

Without entering the debate on the possible legal effects of soft law measures,<sup>50</sup> these acts arguably do not fall within the definition of “acts intended to produce legal effects vis-à-vis third parties” as mentioned in Article 263 TFEU. While in actions for annulment the substance should prevail over the form of the act,<sup>51</sup> the interpretation of the Court is clear in requiring that an act must have legally binding effects to be considered a challengeable act through a direct action according to Article 263 TFEU.<sup>52</sup> Even though scientific opinions of agencies such as EMA influence the Commission decision-making in such a way that these agencies can be considered the *de facto* decision-makers, the pre-decision-making agencies cannot be considered formally to exercise powers having binding legal effects towards third parties.<sup>53</sup>

Although a direct action appears precluded by the wording of Article 263 TFEU, the acts of EU agencies which constitute preparatory acts of final acts adopted by an EU institution are still subject to judicial review indirectly, through the action lodged against the final act which they concurred to produce.

It is settled case law that the invalidity of preparatory acts may lead to the annulment of the final decision.<sup>54</sup> In relation to EU agencies, this principle was stated in particular in the *Artegodan* case,<sup>55</sup> which concerned the withdrawal of marketing authorisations of medicinal products. The decision of withdrawal was adopted by the Commission on the basis of a scientific opinion of the EMA which assessed the risks for human health of the substances at issue. In ruling on the lawfulness of such a

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<sup>50</sup> See Linda Senden, *Soft Law in European Community Law* (Hart Publishing 2004); Merijn Chamon, ‘Le recours à la soft law comme moyen d’éviter les obstacles constitutionnels au développement des agences de l’UE’ [2014] *Revue de l’Union européenne* 152.

<sup>51</sup> *Inter alia*, Case C-322/09 P, *NDSHT v Commission* [2010] EU:C:2010:701, para 46; Joined Cases 16-17/62, *Confédération nationale des producteurs de fruits et légumes v Council* [1962] EU:C:1962:47; Case C-366/88, *France v Commission* [1990] EU:C:1990:348, para 25.

<sup>52</sup> See the interpretation of this notion by the Court, *inter alia*, in Cases 8-11/66, *Société anonyme Cimenteries C.B.R. Cementsbedrijven N.V. and others v Commission*, EU:C:1967:7; Case C-362/08 P, *Internationaler Hilfsfonds eV v European Commission*, EU:C:2010:40, para 52.

<sup>53</sup> About EMA’s opinion: ‘the revised opinion is an intermediate measure whose purpose is to prepare for the marketing authorisation decision. It is a preparatory measure which does not definitively lay down the Commission’s position and is therefore not a challengeable act’, T-326/99, *Olivieri v Commission and EMA* [2003] EU:T:2003:351, para 53.

<sup>54</sup> See, *inter alia*, Joined Cases 12/64 and 29/64, *Ley v Commission* [1965] EU:C:1965:28, para 118; Joined Cases T-10-12 and 15/92, *Cimenteries and others v Commission* [1992] EU:T:1992:123, para 31; Case T-123/03, *Pfizer v Commission* [2004] EU:T:2004:167, para 24.

<sup>55</sup> Joined Cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00 and T-141/00, *Artegodan GmbH v Commission* [2002] EU:T:2002:283. See also T-326/99, *Olivieri v Commission and EMA*.

withdrawal, the Court addressed the issue of the scope of its review. Considering that “the Commission is not in a position to carry out scientific assessments of the efficacy and/or harmfulness of a medicinal product”,<sup>56</sup> the Court recognised the “vital role accorded to an objective and detailed scientific assessment”<sup>57</sup> by the agency, which is called to provide the institution with the evidence of scientific assessment which is essential for its decision-making. From this perspective, the Commission’s acts could be seen as a mere confirmation of the agency’s assessment.<sup>58</sup> Therefore, the scope of the Court’s review included not only the Commission’s exercise of its discretion, but also the legality of the EMA’s scientific opinion.<sup>59</sup> Thus, analysing the agency’s statement of reasons (in a particularly strict way since it related to scientific uncertainty), the Court annulled the Commission’s decision as a consequence of the irregularities observed in the agency’s scientific assessment.<sup>60</sup>

Such indirect judicial review of the agency’s *de facto* decision-making powers is justified by the significance of its acts in the determination of the outcome of the procedure for the adoption of the final act. Considering that “the content of [agency’s] opinions is an integral part of the statement of reasons on which [Commission’s] decisions [are] based”, they are “inextricably linked, the measure forming a whole”.<sup>61</sup> However, where such an effect in the Commission’s decision is not proven, the indirect review of the agency’s act is not granted by the Court.<sup>62</sup>

Despite the indirect review granted thanks to this case law, the solution adopted by the Court still appears to be unsatisfactory. Indeed, in case of exercise of *de facto* decision-making powers, the actual decision-maker remains concealed, attributing factiously the measures to the Commission’s discretion also where it merely rubber-stamps the agencies’ decisions.<sup>63</sup> Moreover, since this review is dependent on the effect of the agencies’ decision on the final outcome, it may leave a gap in the judicial control of exercise of delegated powers of the agencies when they do not have a clear effect on the reviewable measure.<sup>64</sup> Therefore, the jurisdictional remedies accorded in relation to pre-decision-making agencies are not equivalent to those available for genuine decision-making

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<sup>56</sup> Joined Cases T-74/00, *Artegodan GmbH*, para 198.

<sup>57</sup> *Ibid*, para 197.

<sup>58</sup> On this point, see also T-326/99, *Olivieri v Commission and EMA*, para 55.

<sup>59</sup> Joined Cases T-74/00, *Artegodan GmbH v Commission*, para 197.

<sup>60</sup> *Ibid*, para 221.

<sup>61</sup> Case T-240/10, *Hungary v Commission* [2013] EU:T:2013:645, paras 82-91.

<sup>62</sup> Carlo Tovo, *op. cit.* (2016), 357.

<sup>63</sup> Madalina Busuioc, *op. cit.* (2013), 215.

<sup>64</sup> *Ibid*, 216.

agencies, thus making a difference between the two forms of exercise of powers. In the light of the increasing powers delegated *de facto* to the new agencies, this appears not entirely justifiable, entailing the risk of shielding their activities from judicial review.<sup>65</sup>

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<sup>65</sup> Herwig C. H. Hofmann and Alessandro Morini, ‘Constitutional Aspects of the Pluralisation of the EU Executive through “Agencification”’ [2012] 37 *European Law Review*, 442.

### 3. The Intensity of the Review of the Court

The effectiveness and extent of judicial review depends not only on the reviewability of the acts before the Court but also on the intensity of the judicial review exercised by the judges in the contested acts. Indeed, the question on how far the Court goes in assessing the decision and reassessing the elements that lead the author to such a decision is crucial especially in relation to decisions involving discretion. In this regard, it is important to recall that judicial review generally involves a review on law, fact, and discretion.<sup>66</sup> While the Court fully substitutes judgements of the parties in relation to questions of law, the intensity of review of fact and discretion is different since it needs to respect the institutional prerogatives of the author in deciding on the merit.<sup>67</sup> In the balance between full judicial scrutiny and deference to the institutions' assessment lies the standard of review of the Court.<sup>68</sup>

#### 3.1. *The Case Law on Complex Economic or Technical Appraisals of EU Institutions*

In relation to the acts of EU institutions, the Court is called to exercise a comprehensive review of their legality, intensively scrutinising the exercise of their powers.<sup>69</sup> However, when the exercise of discretion involves the evaluation of a complex economic or technical situation, the Court shows a rather deferential approach, which was evident especially in the past.<sup>70</sup>

In particular, in the field of the common agricultural policy (CAP), the Court recognised that the EU institutions enjoyed “a broad discretion” in the choice of appropriate means of action in the light of the various objectives of the CAP.<sup>71</sup> Therefore, “in reviewing the legality of the exercise of such

<sup>66</sup> Paul Craig, *op.cit.*, Chapter 13.

<sup>67</sup> Paul Craig and Grainne De Burca, *op. cit.* (2011), 551.

<sup>68</sup> On the intensity of judicial review see, *inter alia*, Mariolina Eliantonio, ‘Deference to the Administration in Judicial Review - EU report’, (on file from the author), pp. 1-19; Mariusz Baran, ‘The scope of EU Courts’ jurisdiction and review of administrative decisions - the problem of intensity control of legality’ in Carol Harlow, Päivi Leino and Giacinto Della Cananea (eds), *Research Handbook on EU Administrative Law* (Elgar 2017), 292-315; Roberto Caranta, ‘Burden of Proof vs Duty to Give Reasons in Administrative Law’ in Gerencsér Balázs, Berkes Lilla e András Zs. Varga (eds), *A hazai és az uniós közigazgatási eljárásjog aktuális kérdései* (Pázmány Press 2015), 305-323; Karim Kouri, ‘The intensity of judicial review by the Court of Justice of the European Communities in merger cases’ [2007] *Luxembourg journal of law, economics & finance* 114.

<sup>69</sup> Giuseppe Tesaro, *Diritto dell’Unione europea* (4th edn, Cedam 2011), 252.

<sup>70</sup> See, *inter alia*, Case 42/84, *Remia v Commission* [1985] EU:C:1985:327, para 34; Joined Cases 142 and 156/84, *BAT and Reynolds* [1987] EU:C:1987:490, para 62; Case C-7/95, *Deere v Commission* [1998] EU:C:1998:256, para 34; Case C-272/09 P, *KME Germany v Commission* [2011] EU:C:2011:810, para 39; Case C-87/00, *Roberto Nicoli v Eridania SpA* [2004] EU:C:2004:604, para 37.

<sup>71</sup> *Inter alia*, Case 57/72, *Westzucker GmbH v Einfuhr- und Vorratsstelle für Zucker* [1973] EU:C:1973:30; Case C-335/13, *Robin John Feakins v The Scottish Ministers* [2014] EU:C:2014:2343, paras. 56-58. This approach of the Court may find its origin in Article 33 ECSC, now repealed, which stated: ‘the Court may not review the conclusions of the High Authority, drawn from economic facts and circumstances, which formed the basis of such decisions or recommendations, except

discretion, the Court must confine itself to examining whether it is not vitiated by a manifest error or misuse of power or whether the institution in question has not manifestly exceeded the limits of its discretion.”<sup>72</sup> In other words, since the Commission alone is in the position to anticipate and evaluate ecological, scientific, technical, and economic changes of a complex and uncertain nature, the Court cannot substitute its own assessment of the matter for the Commission’s decision.<sup>73</sup>

Such a light approach of the Court was also applied to other policy areas, whenever the EU institution’s decision involves complex economic or technical appraisals. However, in more recent judgments, and especially certain policy areas such as risk regulation and competition,<sup>74</sup> the Court has undertaken a more intensive review of the exercise of powers, applying the test for assessing whether a manifest error occurred in a rigorous way.<sup>75</sup> Such stricter scrutiny of the Court also in cases involving complex economic and technical appraisals was developed, in particular, through a renewed attention to the so-called duty of care, the obligation to state reasons, and the principle of proportionality.

Firstly, since the early 1990s<sup>76</sup> the Court has started to exercise a more circumscribed review on the assessment of the facts done by the Commission, especially in competition law cases. In assessing the factual evaluation of the Commission, the Court reiterated the standard formula for complex appraisals, but at the same time it started to stress the importance of the respect of the rights

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where the High Authority is alleged to have abused its powers or to have clearly misinterpreted the provisions of the Treaty or of a rule of law relating to its application.”. See Alessandra Albanese, ‘Il sindacato sulla discrezionalità nell’ordinamento europeo’ [2018] *Rivista Italiana di Diritto Pubblico Comunitario* 131, 779.

<sup>72</sup> Case C-369/95, *Somalfruit and others v Ministero delle Finanze* [1997] EU:C:1997:562, para 50; Case C-354/95, *National Farmer’s Union and Others* [1997] EU:C:1997:379, para 50.

<sup>73</sup> See, *inter alia*, Case C-87/00, *Nicoli v Eridania* [2004] EU:C:2004:305, para 37; Case T-123/97, *Solomon v Commission* [1999] EU:T:1999:245, para 47; Case T-333/10, *Animal Trading Company (ATC) BV and Others v European Commission* [2013] EU:T:2013:451, para 64.

<sup>74</sup> See, *inter alia*, C-12/03, *Tetra Laval* [2015] ECLI:EU:C:2015:87; C-501/06, *GlaxoSmithKline* [2009] ECLI:EU:C:2009:610; T-13/99, *Pfizer Animal Health* [2002] ECLI:EU:T:2002:209; C-15/10, *Etimine* [2011] ECLI:EU:C:2011:504; C-425/08, *Enviro Tech* [2009] ECLI:EU:C:2009:635. For an analysis of the review in risk regulation, see in particular Ellen Vos, ‘The European Court of Justice in the Face of Scientific Uncertainty and Complexity’, in Bruno De Witte, Elise Muir and Mark Dawson (eds), *Judicial Activism at the European Court of Justice* (Cheltenham 2013), 142-166. In competition law, see Andriani Kalinkiri, ‘What’s in a name? The marginal standard of review of “complex economic assessments” in EU competition enforcement’ [2016] 53 *Common Market Law Review* 1283, pp. 1283-1316; Karim Kouri, ‘The intensity of judicial review by the Court of Justice of the European Communities in merger cases’ [2007] *Luxembourg journal of law, economics & finance* 114.

<sup>75</sup> Mariolina Eliantonio, ‘Deference to the Administration in Judicial Review – EU Report’ (on file with the author), 4; Alessandra Albanese, *op. cit.* (2018), 781.

<sup>76</sup> The seminal case is C-269/90, *Technische Universität München v Hauptzollamt München-Mitte* [1991] EU:C:1991:438. See Herwig Hofmann, ‘The Interdependence between Delegation, Discretion and the Duty of Care’, in Joana Mendes (ed), *Discretion in EU Law* (Hart Bloomsberg 2019).

guaranteed by the EU legal order.<sup>77</sup> Among those guarantees is, in particular, “the obligation [...] to examine carefully and impartially all the relevant elements of the situation in question and to give an adequate statement of the reasons for its decisions.”<sup>78</sup> Thus, through the lenses of the so-called “duty of care” and the obligation to state reasons, the Court proceeds to examine the Commission’s analysis of the technical facts and the interests involved, annulling the decision should the assessment of the EU authority be insufficiently complete or impartial.<sup>79</sup>

In particular, with specific reference to the assessment of scientific facts, the change in the approach of the Court is exemplified by the paradigmatic *Pfizer* case, which involved the acquisition of technical advice from a scientific body. Here, the applicant brought proceedings against a Council regulation which withdrew authorisation for an additive to animal feeding stuff.<sup>80</sup> The decision was based on an opinion of the Scientific Committee for Animal Nutrition on the risk it posed to human health. The Court, after repeating the traditional formula on the limited judicial review of complex technical appraisals,<sup>81</sup> proceeded to carry out a close assessment of the applicant’s claims regarding fact and discretion. In this, it applied the test for manifest error in a way which went far beyond its earlier practice.<sup>82</sup> Therefore, without explicitly departing from its previous case law, the Court has arguably changed the standard of its judicial review through an evolving interpretation of what the assessment of a “manifest error” entails.<sup>83</sup>

Finally, a promising role in limiting the discretion of the EU administration and widening the scope of judicial scrutiny is played by the principle of proportionality. While in some cases the compliance with this principle is problematically equated simply with the lack of manifest inappropriateness of

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<sup>77</sup> Case C-269/90, *Technische Universität München*, para 14. See also Case T-54/99, *max.mobil* [2002] EU:T:2002:20; Case T-342/99, *Airtours* [2004] EU:T:2004:192; Case T-5/02, *Tetra Laval*; Case T-351/03 [2007] *Schneider Electric v Commission*, EU:T:2007:212.

<sup>78</sup> Case C-62/14, *Gauweiler* [2015] EU:C:2015:400, para 69.

<sup>79</sup> Herwig Hofmann, *op.cit.* (2019).

<sup>80</sup> Case T-13/99, *Pfizer v Commission* [2002] EU:T:2002:209. For a detailed analysis of the case, see Ellen Vos, ‘The European Court of Justice in the Face of Scientific Uncertainty and Complexity’, *op. cit.* (2013), 152-160. See also Case C-12/03 P, *Commission v Tetra Laval* [2005] EU:C:2005:87, esp. para 39: ‘Whilst the Court recognises that the Commission has a margin of discretion with regard to economic matters, that does not mean that the Community Courts must refrain from reviewing the Commission’s interpretation of information of an economic nature. Not only must the Community Courts, *inter alia*, establish whether the evidence relied on is factually accurate, reliable and consistent but also whether that evidence contains all the information which must be taken into account in order to assess a complex situation and whether it is capable of substantiating the conclusions drawn from it. Such a review is all the more necessary in the case of a prospective analysis required when examining a planned merger with conglomerate effect.’

<sup>81</sup> Case T-13/99, *Pfizer*, para 166.

<sup>82</sup> Ellen Vos, *op. cit.* (2013), 152-160 ; Antonia Albanese, *op.cit.* (2018), 783.

<sup>83</sup> Mariolina Eliantonio, ‘Deference to the Administration in Judicial Review – EU Report’ (on file with the author), 10; Paul Craig, *EU Administrative Law* (Oxford University Press 2006) , 415-416.

the measure,<sup>84</sup> in other cases this principle has proven to be a valuable tool in the hand of the European judges, especially when associated with the duty of care.<sup>85</sup> Thus, for instance, in *Gauweiler* the Court effectively combined the two principles: it was under the assessment of the proportionality of the measures that the Court recalled the broad discretion enjoyed by the European Central Bank and the obligation “to examine carefully and impartially all the relevant elements of the situation in question and to give an adequate statement of the reasons for its decisions.”<sup>86</sup> Although in that case this examination did not lead to the annulment of the measures at stake, the Court carried out a thorough analysis of the discretion of the institution, demonstrating a significant evolution in the exercise of its scrutiny.<sup>87</sup>

### 3.2. *The Intensity of Review of EU Agencies’ Discretion: The Case of ECHA*

Focusing now specifically on EU agencies, it is arguable that, in the abstract, the intensity of judicial review of their powers may be influenced by two opposing considerations, leading to a more lenient or a more intensive scrutiny.<sup>88</sup> On the one hand, the institutional independence and the specific expertise that agencies enjoy may justify a certain deference towards agencies’ competent assessment, which cannot be substituted by the judgement of an institution lacking the scientific and technical knowledge on the matter.<sup>89</sup> On the other hand, precisely because the agencies enjoy a considerable autonomy from political oversight, this should be compensated by a closer examination of their acts by the courts, aimed at strengthening the accountability of these bodies.<sup>90</sup>

Determining whether the approach of the Court is driven more by the former or the latter consideration, and how intense the actual scrutiny exercised by the Court is, requires a systematic analysis of the judgments concerning the powers of EU agencies. For the purposes of this paper, the analysis is focused on the case law concerning the European Chemical Agency (ECHA). Based in Helsinki, this agency provides scientific and technical expertise in the field of chemicals regulation

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<sup>84</sup> See C-59/11, *Association Kokopelli* [2012] EU:C:2012:442, para 38. The approach of the Court was criticized by AG Kokott in her Opinion in Case C-558/07, *SPCM and others* [2009] EU:C:2009:142, paras 73-77.

<sup>85</sup> Herwig C.H. Hofmann, *op.cit.* (2019).

<sup>86</sup> Case C-62/14, *Gauweiler* [2015] EU:C:2015:400, paras 66-69. For an analysis of the judgment and its implications for the exercise of discretion by EU administrative actors, see Joana Mendes, ‘Discretion, Care and Public Interests in the EU Administration: Probing the Limits of Law’ [2016] 53 *Common Market Law Review* 419.

<sup>87</sup> See also, *inter alia*, Case C-556/14 P, *Holcim (Romania)* [2016] EU:C:2016:207.

<sup>88</sup> For a theoretical and comparative analysis of the judicial scrutiny of agency action, see Tom Zwart, ‘Judicial Review of Agency action: The Scope of Review’ in Tom Zwart and Luc Verhey (eds), *Agencies in European and Comparative Law* (Intersentia 2003), 171-178.

<sup>89</sup> Example of this attitude is the famous US case *Chevron USA v Natural Resources Defence Council* [1984] 467 US 837.

<sup>90</sup> Tom Zwart, *op. cit.* (2003), 172.

and assists in the implementation of the EU's chemicals legislation.<sup>91</sup> Within its tasks, ECHA adopts acts not only of individual application, but also of general application.<sup>92</sup>

The analysis of the case law regarding the acts of ECHA shows that the Court has resorted to the described formula on highly complex scientific and technical facts. In particular, this clearly emerged in a series of parallel judgments of the General Court of 2013,<sup>93</sup> subsequently upheld by the Court of Justice,<sup>94</sup> and became settled case law in later cases concerning the discretion of the ECHA.<sup>95</sup> Quite interestingly, all these cases concerned the identification of a certain substance as a “substance of very high concern” under the REACH regulation,<sup>96</sup> which was qualified as a regulatory act not entailing implementing measures within the meaning of Article 263 TFEU by the Court.

The Court acknowledged that in these cases the “review by the European Union judicature is limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion.”<sup>97</sup> Accordingly, the Court is not allowed to substitute its assessment of scientific or technical facts for that of the agency.<sup>98</sup> Moreover, the broad discretion of ECHA is recognised not only in relation to “the nature and scope of the measures to be taken but also, to some extent, to the finding of the basic facts.”<sup>99</sup> Accordingly, on these aspects the Court exercises only a marginal scrutiny, resulting in the annulment of the act only as far as it is proven that it is manifestly inappropriate.<sup>100</sup> Therefore, it

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<sup>91</sup> 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 [2006] OJ L 396.

<sup>92</sup> The latter were considered by the Court ‘regulatory acts’ within the meaning of Article 263(4) TFEU. See Case T-94/10, *Rütgers and others v ECHA* [2013] EU:T:2013:107, para 57. See also Case T-93/10, *Bilbaina de Alquitranes and others v ECHA* [2013] EU:T:2013:106; Case T-95/10, *Cindu Chemicals and other v ECHA* [2013] EU:T:2013:108; Case T-96/10, *Rütgers and others v ECHA* [2013] EU:T:2013:109.

<sup>93</sup> Case T-93/10, *Bilbaina de Alquitranes*; Case T-94/10, *Rütgers*; Case T-95/10, *Cindu*; Case T-96/10, *Rütgers and others*.

<sup>94</sup> Case C-287/13 P, *Bilbaina de Alquitranes v ECHA* [2014] EU:C:2014:599; Case C-288/13 P, *Rütgers* [2014] EU:C:2014:2176.; Case C-289/10, *Cindu Chemicals* [2014] EU:C:2014:2175; Case C-290/13 P, *Rütgers* [2014] EU:C:2014:2174.

<sup>95</sup> See Case T-177/12, *Spraylat* [2014] EU:T:2014:849; Case T-135/13, *Hitachi Chemical Europe* [2015] EU:T:2015:253; Case T-134/13, *Polynt and Sitre* [2015] EU:T:2015:254; Case T-115/15, *Deza* [2017] EU:T:2017:329; Case T-268/10 RENV, *Polyelectrolyte Producers Group* [2015] EU:T:2015:698.

<sup>96</sup> Article 57 of 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) [2006] OJ L 396.

<sup>97</sup> Case T-93/10, *Bilbaina de Alquitranes*, para 76.

<sup>98</sup> *Ibid.*

<sup>99</sup> *Ibid.*, para 77.

<sup>100</sup> Case T-96/10, *Rütgers*, para 134.

appears that the judicial review is not really intensive, irrespective of the fact that the political control is rather limited.<sup>101</sup>

However, such an approach is tempered by the need to show that “in adopting the act [the EU authorities] actually exercised their discretion, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate.”<sup>102</sup> From this consideration, the Court moves to carry out a lengthy and detailed examination of the elements which constituted the basis of the ECHA’s decision.<sup>103</sup> In this sense, this consideration appears to play a role similar to the one attributed to the duty of care in cases concerning other EU institutions, as a judicial tool to exercise a stricter scrutiny on the agency’s discretion.

Yet, qualitatively, the scrutiny of the Court did not actually review the substance of the Agency’s scientific appraisal. In this regard, particularly enlightening is the comparison with a subsequent judgment of the Court (hereafter, “*Bilbaina II*”),<sup>104</sup> which concerned the same applicants, the same substance and the same methodology disputed in one of the aforementioned cases of 2013 (hereafter, *Bilbaina I*).<sup>105</sup> In *Bilbaina II*, the applicants challenged the classification of the same substance as an Acute 1 (H400) and Chronic 1 (H410) substance by the Commission. After recalling the “manifest error” formula, the Court did not limit its scrutiny to a “procedural review” such as the one carried out in *Bilbaina I* with regard to ECHA’s assessment of all the relevant factors. On the contrary, vis-à-vis the Commission it arguably applied “a much more intrusive standard of scrutiny, blurring the boundaries between the procedural review of any alleged manifest error of assessment and the substantive review of the scientific soundness of the [applied] method”.<sup>106</sup> If it is true that *Bilbaina II* marks a step in the latent evolution of the Court’s interpretation on the duty to take “all relevant factors” into account,<sup>107</sup> it is not less true that, in a very similar scenario, the Court demonstrated more willingness to exercise a more intrusive scrutiny towards the Commission than towards an EU agency.

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<sup>101</sup> Carlo Tovo, *op. cit.* (2016), 364.

<sup>102</sup> Case T-93/10, *Bilbaina de Alquitranes*, para 77.

<sup>103</sup> As expressly recognized by the Court in Case C-419/17 P, *Deza*, para 81. However, for a remarkably short evaluation of the factors and circumstances, see Case T-268/10 RENV, *Polyelectrolyte*, paras 76-79.

<sup>104</sup> Case C-691/15 P, *European Commission v Bilbaina de Alquitranes (Bilbaina II)*, ECLI:EU:C:2017:882.

<sup>105</sup> Case T-93/10, *Bilbaina de Alquitranes*.

<sup>106</sup> Giulia Claudia Leonelli, ‘The fine line between procedural and substantive review in cases involving complex technical-scientific evaluations: *Bilbaina*’ [2018] 55 *Common Market Law Review* 1217, 1242.

<sup>107</sup> *Ibid*, 1240.

Interestingly, the Court does not refer to the duty of care nor to the obligation to state reasons in its review of the agency's assessment.<sup>108</sup> While the relevance of these concepts in limiting the agency discretion appears thus rather marginal in the case law regarding ECHA, a more interesting role is played by the principle of proportionality. In assessing the compliance of the ECHA's decisions with the proportionality principle, the Court contends that the measure is considered not proportionate only if it is "manifestly inappropriate" having regard to the objective of the basic regulation. At the same time, it also emphasises that the agency "has a broad discretion in a sphere which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments".<sup>109</sup> Thus, the Court appears to go even further in its recognition of the discretion of the agency, acknowledging a form of discretion which appears to go beyond the sphere of scientific assessment of facts, problematically recognising a margin of discretion in policy choices which are generally the reserved domain of the legislator.<sup>110</sup> Arguably, this approach raises significant questions not only on the scope of judicial review of the proportionality of the measures, but also on the extent and the kind of discretion delegated to EU agencies.

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<sup>108</sup> Even when expressly raised by the parties, see Case C-650/15 P, *Polyelectrolyte*, para 69.

<sup>109</sup> See Case T-94/10, *Rütgers and others*, para 134.

<sup>110</sup> To use the words of Dominique Ritleng, 'The Reserved Domain of the Legislature. The Notion of Essential Elements of an Area' in Carl Frederik Bergstrom and Dominique Ritleng (eds), *Rulemaking by the European Commission. The New System for Delegation of Powers* (Oxford University Press 2016), 133-155.

#### 4. The Implications of the Limited Review of the Acts of EU Agencies

In the light of the examined case law, it appears that the Court exercises a limited review of EU agencies' powers. Considering in particular the shaky foundations on which the legitimacy of EU agencies is grounded, such findings may raise significant concerns in relation to important constitutional principles which shape the EU institutional structure and to the specific limits which embed the delegation of powers to these bodies.

Firstly, the scope of judicial review is inherently related to the principle of effective judicial protection, which has to be guaranteed by the Court under Article 19 TEU.<sup>111</sup> This fundamental principle of EU law risks to be jeopardised should the Court refrain from exercising an effective judicial review on the activities of EU agencies due to this deferential approach. Considering that the agencies are generally delegated powers precisely to carry out technical and scientific work, the ultimate result would be that most of their activities fall outside the scope of a full review by the Court. It is, thus, questionable whether this is compatible with this principle, with the right to an effective legal remedy enshrined in Article 47 of the Charter<sup>112</sup> and with the basic tenets of the rule of law.<sup>113</sup>

Secondly, the fundamental notion of separation of powers lies at the heart of the issue at stake.<sup>114</sup> Indeed, considering that the Court should not substitute its judgement to the discretion attributed to the EU institutions and bodies, the limited scope of judicial review aims at preserving the prerogatives of the EU executive bodies in policy-making. An excessive deference to their appraisals, however, has the opposite effect of compromising the Court's prerogatives. It fundamentally affects the role of the Court in the "balance of powers which is characteristic of the institutional structure of the community".<sup>115</sup> Drawing the line between reviewable assessments and complex scientific

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<sup>111</sup> See AG Jacobs in Case C-269/90, *Technische Universität München* [1991] EU:C:1991:317. On the principle of effective judicial protection, see C-222/84, *Marguerite Johnston v Chief Constable of the Royal Ulster Constabulary* [1986] ECLI:EU:C:1986:206. On a recent link between Article 19 TEU and 47 Charter of the Fundamental Rights of the EU, see *inter alia* Case C-284/16, *Achmea* [2018] EU:C:2018:158.

<sup>112</sup> Article 47 of the Charter of Fundamental Rights. In this regard, some interesting insights may be inferred also from the case law of the European Court of Human Rights. See, for instance, *Albert and La Compte* (1983) 5 EHRR 533, *Schnaitzer* (1995) ECHR, *Menarini* (2011) ECHR, *Bryan* (1995) ECHR, *Sigma* (2011) ECHR.

<sup>113</sup> See Case 294/83, *Les Verts*.

<sup>114</sup> Herwig Hofmann, *op.cit.* (2019). See also Miro Prek and Silvère Lefevre, 'Administrative, discretion, Power of Appraisal and Margin of Appraisal in Judicial Review Proceedings before the General Court' [2019] 56 *Common Market Law Review* 339, 362.

<sup>115</sup> Cases 9/56 and 10/56, *Meroni* [1958] EU:C:1958:8, 151.

assessments, therefore, amounts to redesigning the division of competences between the judiciary and the executive in the EU legal order.<sup>116</sup>

Thirdly, the limited scope of judicial review of EU powers problematically affects also the institutional balance between the EU agencies and the legislator. Remarkably, this approach of the Court in the judicial review of agencies' acts sits uneasily with the limits on the delegation of powers which were identified in relation to EU agencies. Indeed, the recognition that the ECHA is called to exercise discretion in "political, economic and social choices" is at odds with the prohibition to delegate discretionary powers enshrined in *Meroni*.<sup>117</sup> According to the Court, the respect for the principle of institutional balance demands that the political choices should be reserved for the legislator, and the agencies' empowerment limited to "clearly defined executive powers".<sup>118</sup> Arguably, the scope of discretion acknowledged in *Rütgers* appears to go beyond the traditional limits of the *Meroni* doctrine.<sup>119</sup> Even considering the relaxing of this *Meroni* requirement in the *Short Selling* case, which has sanctioned the possibility to confer on agencies discretionary powers as long as they are "precisely delineated and amenable to judicial review",<sup>120</sup> the compatibility of these two lines of case law appears controversial.<sup>121</sup> This is even more controversial in the light of the fact that in EU law, different from the administrative law tradition of certain national systems,<sup>122</sup> the distinction between "administrative" and "technical" discretion of the public authorities is far from being established,<sup>123</sup> leaving somehow answered the question not only how much discretion is (and can be) attributed to EU agencies, but also which kind of discretion.

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<sup>116</sup> On the interplay between separation of powers and institutional balance, see Jean-Paul Jacque, 'The Principle of Institutional Balance' [2004] 41 *Common Market Law Review* 383, 384; Gerard Conway, 'Recovering a Separation of Powers in the European Union' [2011] 17 *European Law Journal* 304, 319; Paul Craig and Grainne De Burca (eds), *op. cit.* (1999), 58. As an example of the attitude of the Court, see Opinion of Advocate General Bobek in Case C-220/15, *Commission v Germany* [2016] EU:C:2016:534, para 39.

<sup>117</sup> Cases 9/56 and 10/56, *Meroni*, 151.

<sup>118</sup> *Ibid.*

<sup>119</sup> Herwig Hofmann, Gerard Rowe and Alexander Turk, *Administrative Law and Policy of the European Union* (Oxford University Press 2011), 244.

<sup>120</sup> Case C-270/12, *UK v Parliament and Council (Short Selling)*, EU:C:2014:18, para 53.

<sup>121</sup> Merijn Chamón, 'The Empowerment of Agencies under the Meroni Doctrine and Article 114 TFEU: comment on United Kingdom v Parliament and Council (*Short Selling*) and the Proposed Single Resolution Mechanism' [2014] 39 *European Law Review* No. 3, 396. The author interestingly remarks that *Schröder* and *Rütgers* are not mentioned in *Short Selling*. It is equally interesting to remark that in the following cases, *Deza* and *Polynt and Sitre*, *Short Selling* is not mentioned.

<sup>122</sup> See, for instance, Massimo Severo Giannini, *Diritto amministrativo* (Giuffrè 1988), 150.

<sup>123</sup> For some reflections on the nature of discretion in EU law, see Joana Mendes, "Bounded Discretion in EU Law: A Limited Judicial Paradigm in a Changing EU" [2017] *The Modern Law Review* No. 3, 443-472; Miro Prek and Silvere Lefevre, "'Administrative Discretion', 'Power of Appraisal' and 'Margin of Appraisal' in Judicial Review Proceedings before the General Court" [2019] *Common Market Law Review*, 339-380; Joana Mendes (ed), *Discretion in EU Law* (Hart Bloomsberg 2019).

Finally, the limited judicial scrutiny of the Court on the agencies' exercise of discretion casts some doubts on the respect of the requirement expressed in *Short Selling* that the exercise of agencies' powers must be "amenable to judicial review in the light of the legislator's objectives".<sup>124</sup> It is questionable whether the strict supervision required in that case is satisfied by the rather marginal judicial review exercised by the Court in relation to agencies' complex appraisals. This is very problematic in the light of the grounds on which the legitimacy of EU agencies is based. Indeed, in the absence of an express legal basis in the Treaties, the requirements enshrined in *Short Selling*, including judicial review, are not only the limits, but also the crucial conditions for the legality of these bodies under EU law. Limiting the scope of judicial review, thus, risks undermining the position of EU agencies within the EU institutional system.<sup>125</sup>

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<sup>124</sup> Case C-270/12, *UK v. Council of the European Union and European Parliament (Short Selling)* [2014] EU:C:2014:18, para 53. On the point, see Merijn Chamon, *op. cit.* (2014), 396; Herwig Hofmann, Gerard Rowe and Alexander Turk, *op. cit.* (2011), 244.

<sup>125</sup> Carlo Tovo, *op. cit.* (2016), 365.

## 5. Conclusions

This paper has analysed the judicial review of the powers of EU agencies, examining the possibility to challenge the acts of these bodies under Article 263 TFEU and the intensity of the scrutiny of the Court on their assessments. On the first aspect, it was described how the evolution of primary law and of the case law has filled the lacunae that the initial legal framework presented. Yet, some relative gaps may still be recognised, in particular in relation to the activities of pre-decision-making agencies. Also, it is worth recalling that these issues need to be considered in the context of the limited *locus standi* granted to individuals before the Court in general. Not only for the challenge of EU agencies' acts, the admissibility requirements for actions for annulment are interpreted in a particularly restrictive manner by the Court, raising doubts on the effectiveness of access to justice and on the actual completeness of the EU system of legal remedies and procedures.<sup>126</sup>

On the second aspect, although based on a case-law analysis limited to ECHA,<sup>127</sup> the preliminary findings of this research show that the scope of judicial review of EU agencies' powers is explicitly limited since the Court recognises a broad discretion to these bodies in carrying out complex scientific and technical assessments. A detailed discussion of the factors taken into consideration in the agency's assessment may be undertaken by the Court through the need to show that the agency "actually exercised their discretion", potentially counterbalancing the weak control granted under the abovementioned formula. However, in relation to these decentralised bodies, the Court has so far exercised a less intrusive scrutiny than in relation to the European Commission. Moreover, no significant role is played by the duty of care and by the obligation to state reasons, which proved to be useful tools in the hand of the Court to exercise a stricter scrutiny of EU institutions' discretion. With regard to the principle of proportionality, in the analysed case law it appears to be used as a

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<sup>126</sup> See, in particular, the Opinion of Advocate General Jacobs in Case C-50/00 P, *Unión de Pequeños Agricultores v Council* [2002] EU:C:2002:197, para 102. See the criticism in , *inter alia*, Dimitry Kochenov, Grainne De Burca and Andrew Williams, *Europe's Democratic Deficit?* (Hart Publishing 2015); Paul Craig and Grainne De Burca, *op. cit.* (2011), 506-507; Mariolina Eliantonio, Chris W. Backes, C.H. Van Rhee, Taru Spronken, Anna Berlee (eds), *Standing Up for Your Right in Europe: A Comparative Study on Legal Standing (Locus Standi) Before the EU and Member States' Courts* (Intersentia 2013), 45; Paul Nihoul, 'La recevabilité des recours en annulation introduits par un particulier à l'encontre d'un acte communautaire de portée générale' [1994] *Revue trimestrielle de droit européen* 171; Denis F. Waelbroeck and A.-M. Verheyden, 'Les conditions de recevabilité des recours en annulation des particuliers contre les actes normatifs communautaires : à la lumière du droit comparé et de la Convention des droits de l'homme' [1995] *Cahiers de droit européen* 399.

<sup>127</sup> There are, however, some evidence that the approach of the Court is similar in relation to other genuine decision-making agencies, such as CPVO (see Case T-187/06, *Schröder v CPVO* [2008] EU:T:2008:511, upheld on appeal in Case C-38/09 P, *Schröder v CPVO* [2010] EU:C:2010:196) and some pre-decision-making agencies (see Joined Cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00 and T-141/00, *Artegodan*, para 201. See also Case C-120/97, *Upjohn Ltd v The Licensing Authority* [1999] EU:C:1999:14, para 34.)

catalyst for stressing the broad discretion of the agency also in relation to political, economic and social choices, rather than an effective brake to their powers.

As a result, the scope of review of EU agencies' powers appears rather limited, raising significant concerns in relation to some important constitutional principles on which the EU is based. In the light of the problematic implications outlined, a stricter standard of review would appear more in line with the requirements set by the Court for a legitimate delegation of powers under EU law. While it is doubtful that the Court constitutes the appropriate forum for scientific assessments, the development of judicial devices to look closer at the exercise of the discretion - such as the application of the duty of care, the obligation to state reasons and a stricter assessment of the proportionality principle – arguably appears even more necessary in relation to the agencification process.

Equally necessary appears further research on fundamental notions related to the exercise of public action in EU law. Indeed, a better conceptualisation of the notions of merit and discretion, as well as a clearer distinction between administrative and technical discretion, would shed light on the nature of the powers involved and the appropriate extent of the scrutiny of the Court. These notions, and their implications for the limits of the review of the Court, would deserve closer scholarly attention, which this contribution has tried to raise through a first analysis of the case law concerning the ECHA.



## **Judicial Review of the Acts of EU Agencies: Discretion Escaping Scrutiny?**

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