



Oversight of Administrative Rulemaking: Judicial Review

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Abstract: *The role of the courts in the review of administrative rulemaking raises profound questions as to the legitimate interference of courts in the exercise of administrative activities, which are often carried out in the pursuance of a legislative mandate. In contrast to the review of administrative acts of individual application, the Union courts have shown a more hesitant approach in the review of administrative rulemaking activities. This contribution will discuss the review by the Union courts of administrative rulemaking for compliance with procedural as well as substantive standards and will explore whether a convincing rationale for their more deferential attitude to the review of administrative rules can be provided. The article will explore to what extent lessons can be learned from the jurisprudence of the federal courts in the USA, which have struggled, even after the adoption of the Administrative Procedure Act (APA), with similar problems.*

I Introduction

The rise of administrative rulemaking in modern states has had as a consequence that executives escape the constraints of the constitutionally mandated legislative procedures for the adoption of legally binding rules. Courts have found it difficult to employ the tools they have traditionally developed for the review of individual administrative acts also against administrative rules. First, as they are abstract and general, administrative rules usually affect individuals only at a later stage, when concrete administrative decisions are taken. Therefore, many legal systems only provide for incidental review but not direct judicial review. Second, the procedural standards, which courts have set for the adoption of individual administrative acts, such as procedural due process rights, seemed impractical or inappropriate for the review of administrative rules. This was mainly because standards developed for administrative proceedings were modelled on those available in judicial proceedings. Adjudication processes appeared impractical as model for administrative rules affecting large number of people. Moreover, it also seemed inappropriate to impose adjudicatory standards on administrative rules, which in substance resembled more parliamentary legislation than administrative decisions. Third, for the same reasons, it also seemed difficult to develop substantive standards for the adoption of abstract and general rules. The legislative mandate for the adoption of such rules is usually vague and

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couched in general terms allowing the administrative rulemaker to make policy choices. Consequently, courts found it difficult to justify substituting their opinion for that of the rulemaker.

Administrative rulemaking in the EU has seen a similar trend. The considerable increase of Union competences, the complexity of risk and market regulation and the lack of capacity of the Union's legislative process to enact the necessary rules led to a rise in administrative rulemaking in virtually all areas of the EU law. Direct access to the Union courts to challenge administrative rules has to some respect been overcome by the new regime of Article 263(4) TFEU. This provision allows private parties to challenge regulatory acts which do not entail implementing measures solely on the basis that they concern the applicant directly but crucially do no longer require them to show individual concern. Such regulatory acts have been defined as non-legislative acts of general application.¹ Hence, administrative rules provided they do not require implementing measures² will more frequently be the subject of a direct challenge by private parties in the Union courts. This development will inevitably shift the focus of judicial review away from access to the review of the process of the adoption of the Union's administrative rules and the review of their substance. And here, private parties will discover that Union courts, similar to the practice in national legal systems, have shown a more hesitant approach in the review of administrative rulemaking activities than in case of individual administrative acts. Often procedural guarantees, such as the rights of defence, have been denied in cases of administrative acts of general application, or are applied with greater deference, such as the duty to give reasons. The latter approach can also be observed in the application of principles employed for the review of the substance of administrative acts of general application, where deference is the usual approach, be it in respect of the application of general principles of law, the interpretation of the enabling act, the finding of facts or the conclusions drawn from it.

The article will discuss the review by the Union courts of administrative rulemaking for compliance with procedural (section II) as well as substantive standards (section III) and will explore whether a convincing rationale for the more deferential attitude to the review of administrative rules can be provided. Specific attention will be paid to the jurisprudence of the federal courts in the USA, which have struggled, even after the adoption of the Administrative Procedure Act (APA), with similar problems.

II Review of Compliance with Procedural Standards

While Article 263(2) TFEU entrusts the Union courts with the review of whether administrative acts comply with essential procedural requirements provided for in EU Treaties and legislation, many important procedural standards have been developed by the Union courts as general principles of EU law. Such standards are in the first place derived from the courts' understanding of the constitutional rights that

¹ See Case T-18/10, *Inuit Tapiriit Kanatami und Andere v Parliament and Council*, order of 6 September 2011, at para 56 (appeal is pending in Case C-583/11P); Case T-262/10, *Microban International and Microban (Europe) v Commission*, judgement of 25 October 2011, at para 21; Case T-381/11, *Eurofer v Commission*, order of 4 June 2012, at para 42.

² On the interpretation of this requirement in state aid cases, see Case T-221/10, *Iberdrola v Commission*, judgement of 8 March 2012, at paras 46 and 47; Case T-228/10, *Telefonica v Commission*, order of 21 March 2012, at paras 43 and 44.

individuals affected by administrative decision making enjoy irrespective of whether statutes provide for them or not. The Union courts have also derived procedural standards from what is referred to in EU law as sound or good administration.³ The requirement of a careful and impartial examination of a case contributes to a factually accurate decision and thereby to achieving the public interests laid down by its legislative mandate. Equally, the duty to give reasons forces the administration to reflect rationally on its reasoning and enables judges to carry out judicial review. The umbrella term of sound administration can of course tempt judges to go further and impose other judicially inspired standards which in their eyes constitute sound administration, such as the transparency of the proceedings or the consultation of experts or interest groups.

Both categories of procedural standards can of course overlap. The right to a fair hearing is considered as individual right but also contributes to the soundness of the decision-making process. Similarly, the requirement of careful and impartial decision making guards against arbitrary decisions and thereby protects not only the public interest but also individuals. Article 41 CFR reflects this overlap to a certain extent. It is contextually placed within chapter V 'Citizens' rights,' but embodies many public-interest standards and is curiously entitled 'right to sound administration' despite the fact that the Union courts have refused to consider the principle of sound administration as such as an individual right.⁴

One might therefore be tempted to argue that the distinction between rights-based procedural standards and those which are public-interest based is not of great relevance. It is however precisely in the context of administrative rules, where the distinction matters. The Union courts are generally reluctant to impose rights-based standards, such as the rights of defence, in case of administrative rules. They do however impose the duty to diligent examination in its public-interest aspect as procedural standard for the adoption of administrative rules.

This approach raises several questions, which can only be explored in outline below given the constraints of space. First, what is the rationale for the restriction of a rights-based approach to acts of individual application and its exclusion from administrative rules? Second, if the distinction matters, how can it be drawn? Third, to what extent should courts impose public-interest standards on the administration for the adoption of administrative rules? In the following, these questions will be pursued by examining the Union courts' approach in the application of the right to be heard, the duty of careful and impartial examination and the duty to give reasons in the context of administrative rules.

A Administrative Rules and the Right to be Heard

In many European legal systems, individuals do not enjoy the right to be heard in administrative rulemaking. The distinction between adjudication and rulemaking is also crucial for the application of procedural due process enshrined in the 5th and

³ See H. Hofmann, G. Rowe and A. Türk, *Administrative Law and Policy of the European Union* (OUP, 2011), at 190–204.

⁴ See Case T-193/04, *Tillack v Commission* [2006] ECR II-3995, at para 127. See, also H.P. Nehl, *Principles of Administrative Procedure in EC Law* (OUP, 1999), at 37, who rejects the binding effect of the principle of sound administration.

14th Amendment of the US Constitution.⁵ In the EU, the rights of defence have been developed by the Union courts providing individuals with procedural rights in administrative proceedings in the absence of any or insufficient statutory provisions to that effect.⁶ The most important of these fundamental rights,⁷ the right to a fair hearing, has now also been enshrined in Article 41(2) CFR, as part of the right to good administration, which has to be read in light of the case-law of the Union courts.⁸ The Union courts' usual formula is that the right to be heard applies 'in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person.'⁹ It should however be observed that the Union courts apply this formula with great flexibility across the Union's policy sectors and at times deviate from it.¹⁰ The right entitles individuals to be informed about the case against them and to respond. This means in essence that the responsible institution can only rely on those aspects of the case in regard to which the individuals concerned had an opportunity to make their views known. It also allows the individual to have access to one's file, now also enshrined in Article 41(2) CFR, and to respond to third-party comments. Similar to the Supreme Court in the USA, the Union courts are reluctant to apply the right to a fair hearing in a 'legislative' context. This is also reflected in Article 41(2) CFR, which limits the right to a fair hearing to individual measures. And again, as the following survey of the case-law of the Union courts will show, while it is undeniably clear that the jurisprudence of the Union courts 'embodies a normative choice,'¹¹ it is often not quite clear what the Union courts mean by 'legislative.' What is more, the rationale for the exclusion of the right to a fair hearing changes in accordance with the varying definitions of the term 'legislative.'

The General Court in *Atlanta*¹² held that 'the right to be heard in an administrative procedure affecting a specific person cannot be transposed to the context of a legislative process leading to the adoption of general laws'¹³ and hence the right to be heard is excluded 'in the context of a Community legislative process culminating in the enactment of legislation involving a choice of economic policy and applying to the generality of the traders concerned.'¹⁴ The General Court placed considerable emphasis on the fact that the act in issue was adopted by the Community legislator on the basis of the then EC Treaty and found that 'the only obligations of consultation incumbent on the Community legislature are those laid down in the article in question.'¹⁵ The General Court made the point that mandatory consultation of the European Parliament (EP) satisfied the democratic principle, while the equally mandatory consultation of the Economic and Social Committee (ECSC) ensured the

⁵ For a discussion of the scope of procedural due process, see K. Werhan, *Principles of Administrative Law* (Thomson West, 2008), Chapter 3.

⁶ See T. Tridimas, *The General Principles of EU Law* (OUP, 2nd edn, 2006), Chapter 8; P. Craig, *EU Administrative Law* (OUP, 2nd edn., 2012), Chapters 11 and 12; H. Hofmann, G. Rowe and A. Türk, n 3 *supra*, 204–221.

⁷ The rights of defence include the right to be heard, the limited right against self-incrimination, and the limited right of legal professional privilege.

⁸ See Art 6(1)(3) TEU.

⁹ Case 234/84, *Belgium v Commission* [1986] ECR 2263, para 28.

¹⁰ See H. Hofmann, G. Rowe and A. Türk, n 3 *supra*, 206–214.

¹¹ P. Craig, n 6 *supra*, 294.

¹² Case T-521/93, *Atlanta and others v Council and Commission* [1996] ECR II-1707.

¹³ *ibid.*, para 70.

¹⁴ *ibid.*

¹⁵ *ibid.*, para 71.

representation of various groups of economic and social life. Consultation of other parties, such as traders engaged in the banana trade, was not obligatory. This argumentation seems to give significance to the fact that the act was adopted in a legislative procedure providing for the mandatory consultation of the EP and the ECSC, rather than the general applicability of the act.¹⁶

The *Atlanta* judgement therefore only excluded the application of the right to a fair hearing for legislation in form, that is acts adopted in a legislative procedure, but did not exclude it *a priori* for other acts regardless of whether they constituted acts of general application or whether they were based on the Treaty or not.¹⁷ This point seems to have been missed in later cases of the Union courts, which have extended the exclusion of the right to a fair hearing also to legislation in substance, defined as acts of general application, often relying on *Atlanta* as authority in support of their rulings, by wrongly assimilating implementing procedures with legislative procedures.¹⁸ While certain exceptions have been made, mainly for individuals who were directly and individually concerned,¹⁹ the general position in the case-law is that the right to a fair hearing is denied in proceedings leading to the adoption of acts of general application, hence excluding the right from administrative rulemaking.²⁰

In defence of this approach, it would not be sufficient merely to point out that this approach is in line with Article 41(2) CFR and many national legal systems.²¹ On the other hand, the fact that an act of general application adversely affects individuals is not sufficient either to trigger the right of a fair hearing. A distinction needs to be maintained between (fundamental) rights granted to individuals by Union courts regardless of any statutory basis and (political) participation rights which are granted by the political bodies of the Union. While they lack the legitimacy and capacity to draw up general participation rights which involve considerations of policy, Union courts are best placed to determine hearing rights based on arguments of principle.²² Consequently, the instrumental rationale of ensuring a correct outcome and other public interest considerations based on policy,²³ which no doubt will be relevant for the Union legislator in devising participation rights, cannot guide the Union courts in confirming or denying hearing rights.²⁴ An argument based on principle would

¹⁶ On appeal the Court upheld this position of the General Court, see Case C-104/97 P, *Atlanta and others v Commission and Council* [1999] ECR I-6983, paras 37 and 38.

¹⁷ See also Case C-3/00, *Commission v Denmark* [2003] ECR I-2643, at paras 42 to 50, Joined Cases C-439/05 P and C-454/05 P, *Land Oberösterreich*, paras 28 to 44, for requests made under Art 95(5) EC.

¹⁸ See Case T-369/03, *Arizona Chemical and others v Commission* [2005] ECR II-5839, at paras 51 and 73. See also Case T-13/99, *Pfizer Animal Health v Council* [2002] ECR II-3305, para 487. In both cases, the contested act was adopted in a comitology procedure.

¹⁹ Case C-49/88, *Al-Jubail Fertilizer Company and others v Council* [1991] ECR I-3187, para 15. See, also Case T-306/01, *Yusuf and Al Barakaat International Foundation v Council and Commission* [2005] ECR II-3533, at para 324.

²⁰ *Al-Jubail* and *Yusuf* are however difficult to reconcile with the ruling of the General Court in *Pfizer*, in which the General Court rejected the right to a fair hearing to an applicant it considered as directly and individually concerned.

²¹ See also P. Craig, n 6 *supra*, 295.

²² This distinction draws on the reflections in R. Dworkin, *Taking Rights Seriously* (Bloomsbury Academic, 1997).

²³ Such policy considerations might include any of the following: to ensure greater acceptance and better compliance with the rules by those affected; or to give consumers greater confidence in European product regulation; or to enhance the legitimacy of administrative rulemaking more generally.

²⁴ See, also, J. Mendes, *Participation in EU Rule-Making—A Rights-Based Approach* (OUP, 2011), at 229–240. For a different opinion, see P. Craig, n 6 *supra*, 294–298.

therefore have to be based on a dignity rationale.²⁵ This rationale seems particularly relevant for according individuals a right to a fair hearing where an act is based on individual determinations.

It is therefore doubtful that the notion of legislation in substance should serve as basis for the exclusion of the right to be heard. Legislation in substance, defined as acts of general application, has been given a wide and sweeping definition in the case-law of the Union courts. It has been noted that the Union courts only consider an act not to be based on an objectively determined situation, and hence of general application, if it has been adopted ‘on the basis of and with exclusive application to the situation of specific individuals.’²⁶ This cannot be remedied by granting a right to be heard against acts, which, despite their general nature, are of direct and individual concern for the undertakings concerned. This approach would not explain other rulings of the Union courts, such as *Pfizer*. What is more, such an approach seems inadequate. Individual concern in its *Plaumann* interpretation often depends on the procedural guarantees, which the person enjoys by grace of EU legislation.²⁷ This would be incompatible with a rights-based approach. Also, an approach based on the investigative nature of administrative proceedings to establish the right of a fair hearing is not sufficient. While such an approach would be applied to anti-dumping and sanctions cases, it would not apply in those cases where individuals or even Member States initiated the proceedings through notification. This approach is also problematic as the ‘initiated against’ formula which the Union courts use as trigger for the right to be heard is treated by the Union courts separately from the determination of whether an act is of general application.

A more convincing distinction of adjudication and rulemaking to determine the application of procedural due process can be found in the rulings of the US Supreme Court. The Court in *Bi-Metallic* explained that in *Londoner*²⁸ ‘[a] relatively small number of persons was concerned, who were exceptionally affected, in each case upon individual grounds, and it was held that they had a right to a hearing. But that decision is far from reaching a general determination dealing only with the principle upon which all assessments in a county had been laid.’²⁹ Where an EU act is therefore based on individual determinations, as in the sanctions cases or in case of the undertakings concerned in anti-dumping proceedings, then the question as to whether a right to be heard exists is within the province of the courts. This approach would also free the examination from the restrictive *Plaumann* formula used by the Court for individual concern.³⁰ On the other hand, where the act is based on general

²⁵ See J. Mashaw, ‘Administrative Due Process: The Quest for a Dignitary Theory’, (1981) 61 *Boston University Law Review* 885.

²⁶ A. Türk, *The Concept of Legislation in European Community Law* (Kluwer, 2006), at 240.

²⁷ See the different outcomes in Case T-13/99, *Pfizer Animal Health v Council* [2002] ECR II-3305 and T-420/05, *Vischim v Commission* [2009] ECR II-3841.

²⁸ *Londoner v City and County of Denver*, 201 U.S. 373 (1908).

²⁹ *Bi-Metallic Investment Co. v State Board of Equalization*, 239 U.S. 441 (1915), at 446. See E. Chemerinsky, *Constitutional Law—Principles and Policies* (Aspen Publishers, 2nd edn, 2002), at 557, who noted that procedural due process had to be granted where ‘potential factual issues exist concerning a particular individual or group.’

³⁰ It would of course be a separate question, which cannot be pursued in this context, as to whether the ‘initiated against’ formula, which currently seems to dominate the case-law, or the ‘adversely affected’ formula are more adequate as triggers for the right to be heard.

determinations, as is the case of the risk assessments in *Pfizer* and *Arizonal Chemical*, then it is arguably within the province of the political process to decide what participation rights should be made available.

B Careful and Impartial Examination

In the EU, the principle of sound or good administration includes the duty of the competent institution ‘to examine carefully and impartially all the relevant elements of the case.’³¹ It has been developed by the Union courts as procedural guarantee in administrative proceedings to counterbalance the wide margin of appreciation, which the Commission enjoys when making complex evaluations in cases of economic and risk regulation.³² This duty imposes certain standards on how the competent institution assesses information. In *Nölle* the Court pointed out that in anti-dumping proceedings, the Commission had to review ‘the information contained in the documents in the case . . . with all due care required.’³³ It also imposes standards as to how information is collected. The Court in *TU München* made it clear that where the Commission relies on a group to obtain the relevant information, it needs to ensure that the group has the necessary knowledge in the fields relevant for the case.³⁴

The Court has taken this approach further, in particular in risk regulation cases,³⁵ to ensure that the Commission’s decisions are based on sound scientific advice. The Court made it clear in *Pfizer* that ‘a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude arbitrary measures.’³⁶ While this does not imply that in the absence of a statutory requirement, the Commission has to consult a scientific committee,³⁷ the Court has held that ‘it is only in exceptional circumstances and where there are adequate guarantees of scientific objectivity that the Community institutions may, when—as here—they are required to assess complex facts of a technical or scientific nature, adopt a preventive measure . . . without obtaining an opinion from those scientific committees.’³⁸

In contrast to the right to a fair hearing, the Union courts have shown no reluctance to apply the duty of careful examination also in procedures leading to the adoption of acts of general application, hence legislation in substance, regardless of whether the applicants were directly and individually concerned or not. The principle has become a well-established procedural guarantee not only in administrative

³¹ See Case T-326/07, *Cheminova and other v Commission* [2009] ECR II-2685, at para 228. See, also, Case C-505/09 P, *Estonia v Commission*, judgement of 29 March 2012, at para 95.

³² H. Hofmann, G. Rowe and A. Türk, n 3 *supra*, 446. See Case C-269/90, *TU München* [1991] ECR I-5469, at paras 13 and 14; Case C-525/04 P, *Spain v Commission* [2007] ECR I-9947, at paras 58 and 59.

³³ Case C-16/90, *Nölle* [1991] ECR I-5163, para 29

³⁴ Case C-269/90, *TU München* [1991] ECR I-5469, at paras 21–22.

³⁵ The obligation to obtain sound scientific advice is however not limited to risk regulation and can be found in all policy areas. See H. Hofmann, G. Rowe and A. Türk, n 3 *supra*, 451.

³⁶ Case T-13/99, *Pfizer Animal Health v Council* [2002] ECR II-3305, para. 172.

³⁷ In case of statutory ambiguity, such consultation is compulsory, see Case C-212/91, *Angelopharm* [1994] ECR I-171.

³⁸ Case T-70/99, *Alpharma v Council* [2002] ECR II-3495, para 213.

proceedings dealing with market regulation, as in anti-dumping cases,³⁹ but also in those dealing with risk regulation concerning additives in feedingsstuff,⁴⁰ plant-protection products,⁴¹ as well as classification, packaging and labelling of dangerous substances⁴² and the regulation of the CAP⁴³ or those involving sanctions against individuals.⁴⁴

The application of the principle to proceedings resulting in administrative rules seems at first glance surprising given that the principle is closely linked with the right to a fair hearing,⁴⁵ which does usually not apply in such proceedings. Together with the duty to provide a reasoned opinion, they form the basis of the principle of good administration and thereby constitute fundamental procedural guarantees in administrative proceedings. Moreover, both aim to ensure that the institution makes a decision only the basis of complete knowledge of the relevant aspects of the case, and thereby guard against arbitrary decisions. Both therefore share an instrumental rationale in improved administrative decision making and assume importance where substantive review is more limited due to administrative discretion.⁴⁶ However, as the General Court in *Arizona Chemical*⁴⁷ has pointed out, in a procedure leading to the adoption of an act of general application ‘the duty of diligence is essentially an objective procedural guarantee arising from an absolute and unconditional obligation on the Community institution relating to the drafting of an act of general application and not the exercise of any individual right’.⁴⁸ The General Court in this case made it clear that the duty of diligence was ‘primarily an essential and objective procedural requirement, imposed in the public interest’ to ensure administrative regulation ‘meeting the requirements of scientific objectivity and based on the principles of excellence, transparency and independence’.⁴⁹

It is clear from *Arizona Chemical* that the General Court was not willing to provide participation rights beyond those granted as individual rights to a fair hearing, which are essentially limited to forms of adjudication. What is less clear from the ruling is why (objective) consultation obligations, in contrast to (subjective) hearing rights, could not arise from a duty of diligence. This would after all allow the Union courts to structure the procedural process for the adoption of administrative rules and thereby enhance greater transparency and deliberation in administrative proceedings. However, such a broad understanding of due diligence would transgress the boundaries of the judicial realm. While it can be regarded as legitimate for the Union courts to enhance the

³⁹ See Joined Cases C-191/09 P and C-200/09 P, *Council v Interpipe Niko Tube and Interpipe NTRP*, judgement of 16 February 2012, at para 113.

⁴⁰ See Case T-13/99, *Pfizer Animal Health v Council* [2002] ECR II-3305, para 171; Case T-70/99, *Alpharma v Council* [2002] ECR II-3495, para 182.

⁴¹ See Case T-475/07, *Dow AgroSciences and others v Commission*, judgement of 9 September 2011, at para 154.

⁴² See Case C-425/08, *Enviro Tech (Europe)* [2009] ECR I-10035, at para 62; Case T-369/03, *Arizona Chemical and others v Commission* [2005] ECR II-5839, at para 85.

⁴³ See Case T-285/03, *Agraz and others v Commission* [2005] ECR II-1063, at para 49.

⁴⁴ See Case T-256/07, *People's Mojahedin Organization of Iran v Council* [2008] ECR II-3019, at para 139.

⁴⁵ H.P. Nehl, n 4 *supra*, 103–105; T. Tridimas, n 6 *supra*, 406–410.

⁴⁶ T. Tridimas, n 6 *supra*, 407–408.

⁴⁷ Case T-369/03, *Arizona Chemical and others v Commission* [2005] ECR II-5839.

⁴⁸ *ibid.*, para 86.

⁴⁹ *ibid.*, para 88. The General Court made it clear, however, that while in the context of the case the duty of diligence would not confer an individual hearing right, its infringement could be invoked in an action for annulment.

principle of the rationality of administrative rulemaking by requiring a scientific basis for risk regulation to guard against arbitrary administrative decisions,⁵⁰ it is submitted that it is beyond the judicial mandate to impose requirements for the consultation of private interest groups. Public-interest interventions of this kind which involve considerations of policy should be reserved to the Union legislator.

A more reluctant approach to judicial intervention in procedural matters also characterises the more recent jurisprudence of the US Supreme Court. The Supreme Court in *Vermont Yankee*⁵¹ emphatically rejected the attempt by Federal courts to enhance the notice and comment provision in informal rulemaking proceedings in section 553(c) of the APA with greater public participation elements, which are otherwise only available in formal rulemaking procedures.⁵² In its rejection of such judicially imposed hybrid rulemaking, the Supreme Court affirmed the pre-eminence of Congress and, within statutory limits, that of agencies in granting participation rights for rulemaking.⁵³

C Duty to Give Reasons

Under Article 296 TFEU, the duty to give reasons applies to all legal acts of the Union and thereby covers also administrative rules. As part of the principle of sound administration,⁵⁴ it is said to guard against arbitrary decisions.⁵⁵ This duty also furthers the administration of justice by allowing the Union courts to exercise their supervisory function.⁵⁶ For the Union courts, compliance with the duty to give reasons assumes an even greater importance where the substantive review of the measure is reduced due to the discretion the institution enjoys.⁵⁷ In these cases, the Union courts, which review such compliance as a matter of public policy of their own motion,⁵⁸ seem to employ the duty to give reasons as substitute for substantive review.⁵⁹ In addition to the public interest functions of the duty to give reasons, the Union courts have pointed out that reasoned decisions also enable those concerned by an act to defend their rights.⁶⁰ Moreover, interested parties can take note of the reasoning of the institution which adopted the act and adjust their future behaviour accordingly.⁶¹

The Union courts have held that in its statement of reasons, the administration has to set out the factual and legal considerations which underpin its measure. On the other hand, '[i]t is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons meets the requirements of

⁵⁰ Such judicial requirements in turn can lead to enhanced statutory procedural guarantees, see Case T-75/06, *Bayer CropScience and others v Commission* [2008] ECR II-2081, at para 257.

⁵¹ *Vermont Yankee Nuclear Power Corp. v National Resources Defense Council*, 435 U.S. 519 (1978).

⁵² See, in particular, the Opinion of Chief Justice Bazelon's (D.C. Circuit) in *Ethyl Corp. v Environmental Protection Agency*, 541 F.2d 1, 66 (D.C. Cir).

⁵³ On the rise and demise of hybrid rulemaking, see K. Werhan, n 5 *supra*, 220–227.

⁵⁴ See Art 41(2) third indent CFR, which seems to apply however only to administrative decisions.

⁵⁵ H. Hofmann, G. Rowe and A. Türk, n 3 *supra*, 200.

⁵⁶ Case 24/62, *Germany v Commission* [1963] ECR 63, 69. See, also T. Tridimas, n 6 *supra*, 408–409.

⁵⁷ See Case C-269/90, *Technische Universität München* [1991] ECR I-5469, at para 14.

⁵⁸ Case T-102/03, *CIS v Commission* [2005] ECR II-2357, at para 46.

⁵⁹ See M. Shapiro, 'The Giving Reasons Requirement', (1992) *University of Chicago Legal Forum* 179, 182.

⁶⁰ *ibid.*

⁶¹ *ibid.*

Article [296 TFEU] must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question.⁶² The duty does therefore not pursue a dialogue function between affected individuals and the administration.⁶³ Moreover, the Union courts have made it clear that ‘the extent of the requirement . . . to state the reasons on which measures are based, depends on the nature of the measure in question.’⁶⁴ Where the act is of general application, it would be excessive ‘to require a specific statement of reasons for each of the technical choices made by the institution.’⁶⁵ Instead, it is sufficient that the preamble to such an act is ‘confined to indicating the general situation which led to its adoption, on the one hand, and the general objectives which it intended to achieve on the other.’⁶⁶ In contrast, acts of individual application often have to contain greater detail of reasoning.⁶⁷ This is in particular the case for measures imposing fines⁶⁸ or disciplinary measures.⁶⁹

It is however doubtful that the nature of the act can always be the decisive criterion for determining the extent of the duty to provide reasons. The case-law of the Union courts⁷⁰ seems to suggest that the reasoning in an anti-dumping act is ‘assimilated more to the statement of reasons for an individual act, since it must include more than just a general statement about the overall situation.’⁷¹ The Union courts have therefore required that an act of general application which takes account, or should have taken account, of the specific situation of individuals which are directly and individually concerned⁷² by the act has to provide a more in-depth reasoning in order to make the motivation which relates specifically to their situation apparent for these individuals.⁷³ Similar to the reasoning set out above in relation to the right to a fair hearing, it is submitted that it would not be appropriate however to make this approach dependent on the existence of individual concern. Following the rights-based rationale of the duty to give reasons, a more detailed reasoning for administrative rules is required whenever the competent institution makes individual determinations in contrast to more general public-interest based determinations.⁷⁴

⁶² Case T-317/02, *FICF and Others v Commission* [2004] ECR II-4325, para 129.

⁶³ T. Tridimas, n 6 *supra*, 409–410.

⁶⁴ Case 5/67, *Beus* [1968] ECR 83, 95. See, also, Case C-304/01, *Spain v Commission* [2004] ECR I-7655, para 51.

⁶⁵ Case C-122/94, *Commission v Council* [1996] ECR I-881, para 29.

⁶⁶ Case 5/67, *Beus* [1968] ECR 83, 95. See, also, Case T-13/99, *Pfizer Animal Health v Council* [2002] ECR II-3305, para 510; Case C-342/03, *Spain v Council* [2005] ECR 1975, para 55.

⁶⁷ See Case 24/62, *Commission v Germany* [1963] ECR 63; Case T-251/00, *Lagardère v Commission* [2002] ECR II-4825, paras 155–158.

⁶⁸ See Case T-245/03R, *FNSEA and Others v Commission* [2004] ECR II-271, para 49;

⁶⁹ See Case T-11/03, *Afari v European Central Bank* [2004] ECR II-267, para 38

⁷⁰ See Case 53/83, *Allied Corporation v Council* [1985] ECR 1621, at paras 17–19. See, also, Case C-76/00 P, *Petrotub and Republica v Council and Commission* [2003] ECR I-79, at paras 79–91, in which the Court on appeal considered the statement of reasons in the anti-dumping regulation in issue as insufficient.

⁷¹ J. Schwarze, *European Administrative Law* (Sweet & Maxwell, 1992), at 1414.

⁷² See C-76/00 P, *Petrotub and Republica v Council and Commission* [2003] ECR I-79, at para 88; Case C-14/10, *Nickel Institute v Secretary of State for Work and Pensions*, judgement of 21 July 2011, at para 98.

⁷³ See C-76/00 P, *Petrotub and Republica v Council and Commission* [2003] ECR I-79, at para 87.

⁷⁴ This would also explain the reasoning in Case T-13/99, *Pfizer Animal Health v Council* [2002] ECR II-3305, para 510, and Case T-70/99, *Alpharma v Council* [2002] ECR II-3495, para 394, in which the General Court allowed for a more general statement of reasons due to the general application of the act in issue despite the fact that the applicant was directly and individually concerned. On the other hand,

III Review of Compliance with Substantive Standards

While Article 263 TFEU provides specific grounds of review, the Union courts, as in the case of procedural review, have developed constitutional principles of law which govern the substantive review of Union acts. However, it has been observed that the Union courts apply a more marginal form of judicial review in the application of general principles in relation to acts of general application, in contrast to the strict review of administrative decisions.⁷⁵ This deferential approach is usually justified on the ground of the discretion which the competent institution enjoys in the exercise of its powers, mainly due to the ‘political responsibilities’⁷⁶ of the lawmaking institutions, or in cases which involve ‘the evaluation of a complex economic situation,’⁷⁷ or where ‘choices of a political, economic and social nature’⁷⁸ have to be made. Discretion is also relevant for the judicial enforcement of the statutory limits for administrative rules where the Union courts seem to employ a more deferential approach than for acts of individual application. In this respect, it can be observed that the Union courts use the term discretion in a broad sense. While provision for genuine discretion⁷⁹ for the adoption of administrative rules seems rare, the Union courts employ the term discretion also where legislative acts conferring the power to adopt administrative rules use vague and general language. The exercise of broadly drafted enabling powers for administrative action might make it necessary to make complex evaluations of economic and scientific matters. This gives the institution a certain freedom of evaluation as to whether the conditions set out in the authorisation are met. Such ‘evaluative discretion’ encapsulates in fact three different issues for judicial consideration. The first issue concerns the interpretation of the statutory authorisation providing the frame for administrative rules. The second issue relates to the factual determinations necessary for adoption of a rule. And the third issue deals with the conclusions reached in light of those facts. Each of these aspects requires a careful consideration as to the intensity of judicial review that is applied to them and will be explored in more detail below.

A Interpretation of the Enabling Act

The approach of the US Supreme Court on the interpretation of the enabling act for agency rulemaking has oscillated between the understanding that it was for the courts ‘to say what the law is’⁸⁰ and the idea that the agency was better placed to determine the limits of what are often vague provisions in an enabling act. The traditional approach in *Skidmore*,⁸¹ known as *Skidmore* deference, insisted on the courts as the

a more in-depth reasoning is required for those whose individual determinations form the basis of the sanctions regulations, see Case T-85/09, *Kadi v Commission* [2010] ECR II-5177, at para 174.

⁷⁵ A. Türk, *Judicial Review in EU Law* (Elgar Publishing, 2006), at 129–141.

⁷⁶ Joined Cases T-64/01 and T-65/01, *Afrikanische Frucht-Compagnie and another v Council and Commission* [2004] ECR II-521, at para 101.

⁷⁷ Case T-180/00, *Astipesca v Commission* [2002] ECR II-3985, at para 79.

⁷⁸ Joined Cases T-332/00 and T-350/00, *Rica Foods and Free Trade Foods v Commission* [2002] ECR II-4755, at para 155.

⁷⁹ Discretion in this sense is understood as granting the competent institution the freedom to act, even if the statutory conditions for such action are met. Statutory authorisations use the term ‘may’ to indicate such freedom, see Art 107(3) TFEU. P. Craig, *supra* note 6, at 404, terms this classical discretion.

⁸⁰ See the dictum of Chief Justice Marshall in *Marbury v Madison*, 5 U.S. (1 Cranch) 137, 177 (1803).

⁸¹ *Skidmore v Swift & Co.*, 323 U.S. 134 (1944).

ultimate arbiters of what the correct interpretation of an enabling act was, but crucially considered the agency's interpretation as a relevant factor in the canon of statutory interpretation by courts, in particular in case of ambiguity in the enabling act. This was based on the finding that agencies had an 'official duty' and 'specialised expertise'⁸² in the interpretation of their enabling acts. In *Chevron*⁸³ the US Supreme Court further enhanced the deference granted to agencies by ruling that, in the absence of a clear determination of the powers granted to agencies by Congress, the courts would have to defer to the agency's interpretation provided it constituted a permissible construction of the statute.⁸⁴

Similar concerns have occupied the Union courts, the case-law of which can be characterised by an attempt to reconcile the observance of the law as judicial duty with the concern not unnecessarily to impede the effective exercise of administrative rulemaking. In the absence of an autonomous lawmaking power, the Commission's competence to adopt administrative rules is in most cases reliant on an authorisation to issue delegated acts in conformity with Article 290 TFEU or implementing acts in compliance with Article 291 TFEU. The Commission's competence to adopt administrative rules therefore depends on constitutional limits to delegation⁸⁵ and on the scope of the powers conferred on it in the enabling measure,⁸⁶ which can vary in detail.⁸⁷ When determining the scope of the powers conferred on the Commission, the Union courts usually grant the Commission considerable leeway. The standard formula which the Court employs in this respect states that 'within the framework of those powers, the limits of which must be determined by reference amongst other things to the essential general aims of the legislation in question, the Commission is authorised to adopt all the measures which are necessary or appropriate for the implementation of the basic legislation, provided that they are not contrary to it.'⁸⁸ However, the intensity of review varies. In the area of the CAP, the Court made it clear that '[w]hen the Council has thus conferred extensive power on the Commission the limits of this power must be judged with regard to the basic general objectives of the organization of the market and less in terms of the literal meaning of the enabling

⁸² *ibid.*, 139–140.

⁸³ *Chevron U.S.A., Inc. v. National Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

⁸⁴ In *United States v. Mead Corp.*, 533 U.S. 218 (2001) the Supreme Court limited the *Chevron* ruling cases where Congress delegated authority to the agency to make rules carrying the force of law.

⁸⁵ While they insist that the essential elements of a subject matter are reserved to the Union legislator, the Union courts have not enforced this limitation with great vigour. In Case C-355/10, *Parliament v Council*, judgement of 5 September 2012, at para 67, the Court made it clear, however, that the assessment of which elements of a matter should be regarded as essential had to be based on 'objective factors amenable to judicial review'. For a more detailed discussion of the essential elements doctrine, see H. Hofmann, G. Rowe and A. Türk, n 3 *supra*, 227–228.

⁸⁶ The enabling act can be the subject of a plea of illegality under Art 277 TFEU and can therefore be reviewed incidentally by the Union courts.

⁸⁷ In particular in the Common Agricultural Policy (CAP), the Court has considered it acceptable for an authorisation to be 'drafted in general terms' (Case C-240/90, *Germany v Commission* [1992] ECR I-5383, para 41), while in other cases, notably for the amendment of legislative acts, the Court demanded that the Commission's 'power is clearly defined and that the exercise of the power is subject to strict review in the light of objective criteria' (Joined Cases C-154/04 and C-155/04, *Alliance for Natural Health* [2005] ECR I-6451, para 90).

⁸⁸ Joined Cases C-14/06 and C-295/06, *European Parliament and Denmark v Commission* [2008] ECR I-1649, para 51.

word.⁸⁹ At any event, a literal interpretation seems all the more difficult where the Court allows for the enabling provision to be drafted in general terms. Outside the agricultural area, however, the Union courts have taken a stricter line as to the scope of the Commission's implementing powers. In particular, the Union courts have taken care to ensure that the power granted to the Commission to adapt a legislative act to technical progress is not circumvented for other purposes.⁹⁰ When assessing the scope of the Commission's rulemaking powers, the Court therefore attaches considerable importance to the purpose(s) which the legislative act intends to pursue.⁹¹ These observations show that while the Union courts' approach for the determination of the statutory limits for administrative rulemaking differs in principle from that of the US Supreme Court, in that it does not admit to any deference to administrative interpretation of the enabling act, the Union courts in practice provide considerable leeway for administrative rulemaking provided this can be accommodated by the purpose of the enabling act. In any event, given its complexity and essentially judicial nature, it is submitted that the exercise of this judicial duty should not be regulated by general legislation.

B Standard of Judicial Review of Facts

While courts consider the interpretation of the statutory framework as within their remit, they are more reluctant to review the factual findings which the enabling act requires administrative bodies to make before reaching a decision. Judicial review of factual determinations is guided by the principle that it is not for the courts to substitute their view for that of the administrative fact finder. On the other hand, the rule of law requires that decisions are not arbitrary, which is the case where they lack a sufficient and coherent evidentiary basis.

The US experience has shown that it has proved difficult for lawmakers to lay down a detailed standard for judicial review of facts. The APA has only decided to lay down a more specific test for the review of factual findings in formal proceedings, which requires courts to invalidate such findings if they are not supported by 'substantial evidence.'⁹² Most administrative rules by agencies in the USA are however adopted in informal proceedings, which follow the 'notice and comment' approach, but crucially are not made 'on the record.' Factual determinations in such proceedings are reviewed on the basis of the 'arbitrary and capricious'⁹³ standard, which traditionally has led the federal courts of appeal to apply a more deferential course of review than the 'substantial evidence' review.⁹⁴ The differences between the two standards might however be in reality more apparent than real. While it lays down certain standards

⁸⁹ Case 23/75, *Rey Soda v Cassa Conguablio Zucchero* [1975] ECR 1279, para 14. See, also, Case 22/88, *Vreugdenhil* [1989] ECR 2049, para 16.

⁹⁰ See Joined Cases T-74/00 etc, *Artogodan and Others v Commission* [2002] ECR II-4945; Case C-93/00, *European Parliament v Council* [2001] ECR I-10119.

⁹¹ Compare Joined Cases C-14/06 and C-295/06, *Parliament and Denmark v Commission* [2008] ECR I-1649 with Case C-448/06, *cp-Pharma* [2008] ECR I-5685.

⁹² On the distinction of the term 'substantial evidence' as standard of proof before the adjudicator in section 556(d) APA and as scope of judicial review in section 706(2)(E) APA, see *Steadman v SEC*, 450 U.S. 91 (1981) as per Justice Brennan, at 98–100.

⁹³ See section 706(2)(A) APA.

⁹⁴ See, however, Justice Scalia's opinion for the D.C. Circuit in *Association of Data Processing Service Organizations, Inc. v Board of Governors of Federal Reserve System*, 745 F.2d 766 (D.C.Cir. 1984).

for agencies to make factual determinations, be it ‘substantial evidence’ for formal proceedings or ‘arbitrary and capricious’ for informal proceedings and entrusts the enforcement of the standards to the courts, the APA does not prescribe how the courts determine that an agency has met the prescribed standard. The Supreme Court’s reasonableness approach applied in formal proceedings⁹⁵ arguably also forms the basis of the review of whether factual determinations meet the ‘arbitrary and capricious’ standard in informal proceedings, including administrative rulemaking. What ultimately distinguishes the review of factual determinations in administrative rulemaking from those in adjudication is that the former are often made in informal proceedings providing courts with ‘greater amorphousness of the administrative record’ seamlessly ‘interwoven with administrative policy judgments.’⁹⁶

These considerations are a useful background to the approach of the Union courts to the review of factual determinations in EU administrative rulemaking. The Union courts have consistently held that ‘where a Community authority is required to make complex assessments in the performance of its duties, its discretion also applies, to some extent, to the establishment of the factual basis of its action.’⁹⁷ While this seems to indicate a deferential approach based on a ‘manifest error’ test, other cases indicate a stricter standard of judicial review for factual determinations. In *Gowan*, the Court pointed out that judicial review included *verification* that ‘the facts admitted by the Commission have been accurately stated.’⁹⁸ And in *Dow AgroSciences*, the General Court held that any assessment of risk to public health had to be based ‘on the most reliable scientific data available and the most recent results of international research.’⁹⁹ The General Court in this case also made it clear that any limits of judicial review in relation to the assessment of complex facts (see below C) by the competent EU institution would not affect ‘their duty to establish whether the evidence relied on is factually accurate, reliable and consistent, 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.’¹⁰⁰

Such judicial statements offer us insights into the quality and quantity of factual evidence to be expected by the Union courts in reviewing factual determinations by the EU administration. However, they do not amount to a coherent standard of judicial review of factual determinations nor do they provide us with an explanation of how the Union courts determine whether the administration has complied with such standards.¹⁰¹ It can in this respect only be observed that the General Court seems to engage in a more probing enquiry, while the Court of Justice seems to be satisfied with a reasonableness approach.¹⁰² In either case, it seems however clear that the Union courts employ more than a ‘marginal error’ test but less than strict review. This demonstrates a need for a clearly pronounced test for judicial review of factual

⁹⁵ *Universal Camera Corp. v National Labor Relations Board*, 340 U.S. 474 (1951).

⁹⁶ K. Werhan, n 5 *supra*, 323–324.

⁹⁷ Case T-13/99, *Pfizer Animal Health v Council* [2002] ECR II-3305, para 168. See, also, Case C-425/08, *Enviro Tech (Europe)* [2009] ECR I-10035, para 62.

⁹⁸ Case C-77/09, *Gowan* [2010] ECR I-13533, para 56.

⁹⁹ Case T-475/07, *Dow AgroSciences and others v Commission*, judgement of 9 September 2011, at para 85.

¹⁰⁰ *ibid.*, at para 153.

¹⁰¹ The case-law also seems to lack a standard of proof which has to be employed by the administration for factual findings. The ‘convincing evidence’ test applied in competition cases, which is discussed by P. Craig, n 6 *supra*, at 432–433, cannot without difficulties be transferred to administrative rulemaking.

¹⁰² See P. Craig, n 6 *supra*, at 438–439.

determinations and a clarification about the judicial test for meeting this standard. While the former could suitably be enshrined in general legislation, the US experience shows that the latter should be left to the courts. It is submitted that stricter judicial standards need to be used for reviewing determinations of an individual nature than those of a general nature to protect the process rights of individuals.

C *Judicial Review of the Assessment of Facts*

As enabling acts provide the competent administrative bodies usually with wide latitude in the adoption of administrative rules, the assessment of facts is often a matter of judgement and involves policy considerations on the part of the responsible administrative body. The role of judicial review is in this respect more limited. Courts, in particular when they exercise general and not specialised jurisdiction, have neither the constitutional mandate nor the political legitimacy to substitute their policy choice for that of the administration. All the same, legality review obliges courts to ensure that the administration engages in reasoned rulemaking to prevent arbitrary rules being adopted. The proper judicial role is therefore to reinforce the benefits of administrative rulemaking, which often lie in their specialisation and expertise.¹⁰³ It can however be observed that the attitude of courts varies over time and place depending on what they perceive as dangers of administrative rulemaking, such as lack of process participation or agency capture.

The US experience with agency rulemaking demonstrates these points more clearly. By applying a reasonable basis test, the Supreme Court initially showed considerable deference in the application of the arbitrary or capricious standard (see section 706(2)(A) APA)¹⁰⁴ continuing its highly deferential approach before the enactment of the APA.¹⁰⁵ In *Overton Park*¹⁰⁶ the Supreme Court endorsed however a stricter approach to substantive review. The Supreme Court found that while they could not substitute their opinion for that of the agency, which could rely on a legislative mandate and expertise, reviewing courts had to ensure that the agency engaged in reasoned decision making. The ‘hard look’ doctrine therefore entrusts reviewing courts with the task of ensuring that the agency itself has taken a hard look at the relevant issues. The reviewing courts will invalidate agency action if it considers it irrational or implausible, when the agency fails to give adequate consideration to the relevant issues, or where it fails to explain its decision.¹⁰⁷ The ‘hard look’ doctrine has been described as a flexible instrument which can be varied according to what is at stake.¹⁰⁸ Agency rulemaking which deals with politically controversial issues will therefore meet with more intensive review than routine agency decisions.¹⁰⁹

On the whole, a similar development can be observed in the EU. The Union courts have pursued a more marginal review of administrative rules, in particular where they

¹⁰³ See the views of judge Leventhal in *Greater Boston Television Corp. v FCC*, 444 F.2d 841 (D.C.Cir. 1970).

¹⁰⁴ See *SEC v Chenery Corp.* (Chenery II), 332 U.S. 194 (1947).

¹⁰⁵ See *Pacific State Box & Basket Co. v White*, 296 U.S. 176, 185–186.

¹⁰⁶ See *Citizens to Preserve Overton Park, Inc. v Volpe*, 401 U.S. 402 (1971).

¹⁰⁷ See *Motor Vehicle Manufacturers Association v State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983).

¹⁰⁸ K. Werhan, n 5 *supra*, at 359.

¹⁰⁹ *ibid.*, at 359.

involve the assessment of complex economic and scientific matters.¹¹⁰ The Union courts have limited their review to whether ‘the exercise by the institutions of their discretion in that regard is vitiated by a manifest error or a misuse of powers or whether the institutions clearly exceeded the bounds of their discretion.’¹¹¹ Similar to the US experience, it can be observed that the manifest error test has been applied with varying intensity over time.¹¹² While the Union courts have intensified review over administrative rules in the common policy areas, it is in particular the General Court in the field of risk regulation which has considerably expanded and intensified the scrutiny of the assessment of facts.¹¹³ Judicial review includes here not only the reasoning process of the Commission, which often makes the ultimate decision, but also that of scientific committees,¹¹⁴ on which the Commission relies for expertise.

The principle of careful and impartial examination provides here a crucial link between its procedural and its substantive dimension. While the former ensures that the Commission obtains appropriate scientific advice, the latter ensures that the Commission has considered all the relevant issues.¹¹⁵ It should however be noted that while it can overcome statutory deficits in the provision of expertise for administrative rules of the EU, the principle of careful and impartial examination cannot be a substitute for a statutory notice and comment procedure. It is often the comments received in the notice and comment procedure which will allow the reviewing courts to scrutinise whether the agency has adequately considered alternative views.¹¹⁶ General statutory provisions as to public participation in EU administrative rulemaking would therefore not only enhance the legitimacy of the process but would also ensure that the Union courts have an adequate administrative record for substantive review.¹¹⁷ This in turn would lead to a more detailed statement of reasons for administrative rules than is currently required by the Union courts, which have held that ‘if the contested measure clearly discloses the essential objective pursued by the institution, it would be excessive to require a specific statement of reasons for the various technical choices made’.¹¹⁸

IV Conclusion

The deferential approach of the Union courts in relation to the review of administrative rules reflects to a considerable degree their understanding of the nature of administrative rulemaking as a form of legislation. This is certainly contestable, as the Commission has political responsibility to deal with complex economic and technical issues, also in case of adjudication, where the Union courts, in particular in

¹¹⁰ Case T-13/99, *Pfizer Animal Health v Council* [2002] ECR II-3305, para 169.

¹¹¹ *ibid.*, para 169. See, also, C-425/08, *Enviro Tech (Europe)* [2009] ECR I-10035, para 47.

¹¹² See P. Craig, n 6 *supra*, at 441–445.

¹¹³ It should however be pointed out that unlike its approach in competition law, the General Court has however taken care not to substitute its opinion for that of the competent body. See Case T-342/99, *Airtours v Commission* [2002] ECR II-2585; Case T-05/02, *Tetra Laval BV v Commission* [2002] ECR II-4381.

¹¹⁴ See Joined Cases T-74/00 etc, *Artegodan and others v Commission* [2002] ECR II-4945.

¹¹⁵ See Case C-77/09, *Gowan* [2010] ECR I-13533, para 57.

¹¹⁶ See, also, P. Craig, n 6 *supra*, at 443–445.

¹¹⁷ See the dictum of a federal court of appeals in *United States v Nova Scotia Food Products Corp.*, 568 F.2d 240, at 249 (2d Cir. 1977) that meaningful judicial review ‘requires an adequate record.’

¹¹⁸ Case C-14/10, *Nickel Institute v Secretary of State for Work and Pensions*, judgement of 21 July 2011, para 99.

competition cases, apply a more rigorous review. Moreover, administrative rulemaking procedures lack the democratic legitimacy of legislative procedures. All the same, the deferential approach of the Union courts can be justified on the basis of considerations of the proper function of the judicial and political institutions in the Union not only in relation to procedural standards but also substantive standards for administrative rulemaking. The Union's political institutions have to respect the constitutional mandate of courts to enforce process rights, such as the right to a fair hearing. Inasmuch as administrative rules make individual determinations, it is submitted that it is within the province of the courts to ensure that affected individuals are heard and that the reasons are sufficiently reflective of such views. On the other hand, courts need to respect the responsibility of the Union's political institutions to provide for public participation. The judicially created duty to examine carefully and impartially does not affect this distinction, as its procedural demands enhance the rationality of the decision but cannot be used to grant general participation rights. These considerations are also relevant for assessing substantive standards of judicial review. Stricter review is required for constitutional issues, such as compliance with Articles 290 and 291 TFEU and the interpretation of the statutory framework for administrative rulemaking, whereas less intense scrutiny is warranted for the review of factual findings or the assessment of such facts. This view also has consequences for the political determination of rules for administrative rulemaking, be that in specific Union legislation or in a more general EU code. The political institutions have to assume responsibility for process legitimacy through enhanced public participation in administrative rulemaking. An enhanced public participation in administrative rulemaking, such as notice and comment, will also be beneficial for judicial review, as it provides the Union courts with a better record on the basis of which they can assess whether the administrative rules before them are the outcome of rational, rather than arbitrary, decision making.

First submission: September 2012
Final draft accepted: October 2012