A legal perspective on Regulatory Impact Assessments

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I. Introduction

In the last decades, regulatory reform programs have been adopted widely, placing regulatory impact assessments central as the ‘key regulatory improvement tool’. In their wake, a commercial industry of IA consultants emerged, along with much scholarly attention, mainly in the field of social and economic sciences and public administration. These studies generally overlook the legal implications of regulatory reform, although a small circle of jurists did trace out the legal aspects of regulatory reform in general, and IAs in particular.

By introducing a so-called ‘legal validity test’, Purnhagen and Feindt showed the relevance of a legal perspective for the structuring and functioning of the IA. They argued that RIAs should reflect the goals and values prioritized in the EU Treaties, such as fundamental rights, health protection, consumer protection and environmental protection. These determine the type of data the Commission should collect and the weight attached to them in the overall balance of options.

Likewise, in national legal systems, constitutions give weight to fundamental rights in general, and specific values, such as health protection, gender equality, children’s rights and protection, consumer protection, environment protection, etc. Some of these values have indeed acquired specific attention in the regulatory process in the form of, for example, gender impact assessments or youth impact assessments. While the general trend is to include them in a broader impact assessment, the duty to carry out specific IAs may acquire firmer legal ground. For example, in Flanders, the general IA is laid down in administrative guidelines, whereas the law imposes the duty to measure the impact on children and youth whenever a bill is likely to directly affect persons under twenty-five.

The core of legal analysis, however, lies in legality tests. Hence, legal scholars are mainly interested in the question of whether there is a legal duty to carry out impact assessments and whether this duty is enforceable before the court. At the theoretical level, arguments have been developed pro and contra judicialization of regulatory reform instruments. At the more empirical level, the case law of courts has been analyzed to examine whether courts indeed engage with the procedural aspects of law reform. In this paper, I will combine both strands and rely on what courts do in fact to assess the validity of theoretical arguments. To this end I will (III) present arguments contra and pro judicialization of impact assessments before (IV) exploring whether these arguments stand ground. First, however, (II) three preliminary notes will outline the focus of this paper.

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2 For an overview see A. Meuwese and S. van Voorst, ‘Regulatory Impact Assessment in legal studies’, in C.A. Dunlop and C.M. Radaelli (eds), Handbook of Regulatory Impact Assessment (Cheltenham, Edward Elgar 2016) 21-32. The authors, however, take a formal approach, defining ‘legal scholarship’ on the basis of institutional affiliation or publication venue, rather than methodology.


4 See, for example, in the Netherlands: https://www.kcwj.nl/sites/default/files/iaa_booklet_english.pdf (last accessed: 10 August 2017).

5 Art. 4 Flemish Community Decree of 20 January 2012 on a renewed youth- and children’s rights policy.
II. Delineation: two preliminary remarks

The focus of this paper is on the judicialization of impact assessments and, more specifically, of regulatory impact assessments.

1. Distinguishing legal analysis from social and economic impact assessments

First, this paper is mainly concerned with impact assessments as key instruments of the regulatory toolbox. Several definitions of IAs are circulating, that differ only in phrasing or detail. Yet, it is important to agree on a sharp definition to avoid mingling legal analysis and non-legal impact assessment.

Dunlop and Radaelli define IAs as ‘a systematic and mandatory appraisal of how proposed primary and/or secondary legislation will affect certain categories of stakeholders and other dimensions’, such as the economy, trade, gender, health, employment, poverty, the environment or climate. This activity presupposes certain skills that are generally not part of the legal training completed by judges. The International Association of Impact Assessments, in turn, defines it more broadly as the ‘process of identifying the future consequences of a current or proposed action’. In the latter definition, the identification of legal obstacles and consequences can also be considered a type of impact analysis. Such legal analyses are common ground in most legal systems, carried out by administrative staff, parliamentary councils, or external advisory bodies such as the Council of State in France, Belgium, Luxembourg and the Netherlands. Including these legal ‘impact assessments’ would lead us away from the main topic. While the question of whether such legal reviews are effective in arming legislation against judicial invalidation remains of interest, the most challenging issues regarding judicialization of regulatory instruments concern the judicialization of non-legal assessments.

Obscuring the difference between legal analysis and non-legal impact assessments is not without risk.

One example is the legal impact assessment carried out in preparation of the implementation of EU Directives in national systems. In Belgium a circular requires the federal administrations to carry out an ‘impact analysis’ already at the stage of draft directives. Closer reading reveals that the circular merely alludes to the legal impact: which existing laws and regulations are affected, which provisions have to be amended? While this is a necessary but purely legal-technical exercise, the qualification as ‘impact assessment’ is misleading. Where impact assessments are considered to range amongst the most decisive factors for the successful transposition of Directives, the circulars give the false impression that the Belgian administration is well-prepared.

Another example is the fundamental rights check as part of the IA. In the EU, this is an example of how judicial enforcement impacts upon the structure of the IA. In its guidelines, the Commission pointed out that this checklist was a response to the duty articulated and sanctioned by the Court of Justice of the European Union (ECJ) for the EU institutions ‘to prove – in the light of the fundamental rights protected by the Charter – that they have carefully considered different policy options and

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7 This is the definition used by the International Association for Impact Assessment, see http://www.iaia.org/ (last accessed: 10 August 2017)
8 See the circular: Instructions for the transposition of European directives in Belgium, February 2016, at p. 35
9 G. Diericks, P. Bursens and S. Helsen, How to Explain the Belgian Integration Paradox? (University of Antwerp 2001)
have chosen the most proportionate response to a given problem’. The idea of human rights impact assessments has also won ground in national states. For example, the Finish governmental action plan on fundamental rights includes the development of assessment of fundamental and human rights impacts in statute drafting.

The danger of the inclusion of fundamental rights checks in IAs, while advocated by NGOs, lies in the mixing of compatibility checks and impact assessments. The risk is that fundamental rights infringements are considered acceptable in the overall balance, for example when economic benefits are considered to weigh more heavily. This is more likely if the fundamental rights check in the IA is structured identical to the compatibility test, as is the case in the EU: questions such as what fundamental rights are affected, whether they are absolute or not, whether interference is necessary to achieve the desired aim of general interest, whether it is proportionate and whether the essence of the concerned fundamental right is preserved, are not different from the steps that build the compatibility check.

Instead, the compatibility check should be clearly distinguished from the IA. The goal of creating awareness of fundamental rights issues in the daily practice of lawmaking, can be achieved by close cooperation of the administrative staff responsible for the compatibility check, on the one hand, and the staff conducting the IA, on the other. The compatibility check, then, may determine which data should be collected in the IA to assess whether the measure is indeed necessary and proportional. For example, legislation that restricts home education infringes upon the right to education with respect of the parents’ religious and ideological convictions, but is often justified on the assumption that children that receive their education at home are socially isolated. The impact assessment should examine empirical evidence for the assumed impact of non-interference.

2. Regulatory Impact Assessments

In most legal systems, the judicial review of executive measures against procedural requirements is not controversial. This is especially so where individual measures are concerned. The duty to organize environmental impact assessments in the process of specific permits and urbanization projects is well-established and widely reviewed. By contrast, this paper focuses on regulatory impact assessments, as part of the decision making procedure of acts of general scope.

In presidential systems, and the US in particular, impact assessments and judicial review are based on theories of delegation: they are established to control agencies that have received broad rule making powers. In the US, the Administrative Procedure Act (APA) allows courts to set aside agency regulation if the regulation is ‘arbitrary and capricious, an abuse of discretion, or otherwise not in...
accordance with the law’. The APA does not mention impact assessments, but administrative judges do rely on IAs to decide disputes and Executive Orders regularly require agencies to carry out IAs. On this basis, the US courts have over the years developed standards for the review of such regulations, to compensate for the lack of electoral accountability. Still, even there the increasing judicializing of the administrative procedure has been criticized for risk of ossification of the decision making process. 

In the EU, the Better Regulation program was presented as a tool to enhance the legitimacy of EU lawmaking. A more prosaic view is that the program, including IAs and consultations, serves to reinforce the position of the Commission in the legislative process. In national parliamentary systems, the legislature already relies on strong democratic credentials so that regulation reform programs and IAs are seen as tools to give extra accountability and strengthen the competitive position of the country. In these contexts, judicialization meets with even stronger opposition. Leaving aside the debate between legal and political constitutionalists on the advisability of judicial review of parliamentary acts, it is noted that even in legal systems where courts have the power to invalidate acts of parliament, the review of procedural aspects is not self-evident. While we could argue that procedural review is less intrusive, as it avoids second-guessing policy outcomes, it is nonetheless often met with more resistance based on concepts of parliamentary sovereignty and the separation of powers that consider the internal workings of Parliament as sacrosanct. Hence, even in the US, procedural rationality review of legislative acts under the due process clauses is much more deferential than the so-called ‘arbitrary and capricious review’ of agency actions.

In this paper, the focus is on the European debate. In contrast to the US, regulations are rarely agency-based, and the development of legislative policies as well as the debate on their reviewability is of a more recent date. Therefore, while taking into consideration the US experience to formulate arguments pro and contra judicial enforcement, the paper’s focus is on national legal systems in Europe and the European Union. The empirical analysis will mainly, but not exclusively, resort to the ECJ case law, as this is where impact assessments are examined most thoroughly.

3. Alternatives for judicial review

Considering various potential drawbacks, presented in Section III, critics point to alternatives for judicial review. IAs are part of the default administrative procedure. In several countries – Germany, the Netherlands, the UK and the EU, to name but a few – regulatory oversight bodies have been established to check the quality of RIAs. The argument, however, does not necessarily make judicial review redundant. Administrative oversight and legal review can complement each other. The exigency of judicial review depends upon how well administrative oversight functions. Courts, then, come into play if something goes wrong at the administrative plane.

The argument is not discussed further in this paper, since its correctness cannot be tested through an examination of case law but through an empirical analysis of how these oversight bodies function.

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16 Meuwese and van Voorst, supra note 2, 22-23.
17 See further, section III.
Hence, while we can assume that integrating IAs and IA checks as standard procedural steps is more efficient than external legal overview \textit{ex post}, much depends on how autonomous and precise these bodies actually work. For example, the EU Regulatory Scrutiny Board is still closely linked to the Commission, with members that are almost exclusively former members of the Commission, and its negative opinions are not binding upon the Commission. Hence, Meuwese and notice that the Board, navigating under ‘inevitable political pressures’, does not position itself as an alternative to a judicial review mechanism but that, on the contrary, the threat of judicial review might lead the Commission to taking the RSB more seriously.\footnote{A. Meuwese and S. Gomtsian, ‘Regulatory Scrutiny of Subsidiarity and Proportionality’, (2004) 22 Maastricht Journal of European and Comparative Law 489.}

Consequently, in this paper, the starting point is that administrative regulatory oversight is recommendable, but does not make the judicial review topic redundant. Instead, administrative and judicial oversight are considered complementary functions.

\section*{III. Judicial enforcement of the duty to carry out impact assessments: identification of arguments and counterarguments}

In literature, we can identify four arguments against the judicial review of the duty to carry out impact assessments. Each of these arguments, however, can be turned around in favor of judicial review. Each set of argument and counterargument is ranged according to the values underpinning the debate: 1) legitimacy, 2) neutrality, 3) efficiency and 4) expertise. In this section, the arguments and counterarguments are discussed on a theoretical plane. In the next section, an empirical analysis will establish whether, for each pair, the argument \textit{pro} or \textit{contra} judicial review is most convincing within the European context.

\subsection*{1. Legitimacy: the political primacy argument}

Following the political primacy argument, judicial enforcement of the duty to give scientific evidence risks undermining political primacy by substituting legitimate political decision making for scientific reasoning.\footnote{M. Dawson, \textit{New Governance and the Transformation of European Law} (Cambridge, Cambridge University Press 2011) 261.} In essence, the argument opposes the rise of evidence-based law making as such, viewing judicial review merely as a catalyst to reinforce this trend.

The argument is of less importance with regard to agency regulations which are generally of a more technical nature and where, more importantly, procedural requirements and judicial review compensate for electoral accountability deficits. For example, in the US, judicial regulatory oversight is justified as a means to check whether the agency’s action is in accordance with the will of the political branches.\footnote{F Anderson, MA Chirba-Martin \textit{et al}, ‘Regulatory Improvement Legislation: Assessment, Cost-Benefit Analysis, and Judicial Overview’, (2000) 11 Duke Envtl. L \& Pol’y F, 109.} The argument gathers weight when it comes to judicial oversight of Parliamentary Acts.

Where Parliament is involved in the regulatory procedure, it is the quality of representative lawmaking that is at stake. While advocates of judicial review agree that courts should not replace political decision making, they argue that democratic legitimacy is not exclusively based upon electoral accountability, but also on the presumption that parliaments represent ‘the people’s will’ through a public, inclusive and informed debate, based on political preferences, but also on facts and
evidence. An impact assessment is a tool that enables such debate. Courts may reinforce the legitimacy of a specific political decision by confirming that it was based on facts and evidence, or they may reinforce the legitimacy of political decision making in the longer term by urging the legislature to more evidence-based decision-making. At least, judicial review will force the legislature to explain why a certain measure is taken, leading to more careful and rational lawmaker.24

2. Neutrality: the market-liberal bias argument

Regulatory reform is mostly linked to policy goals of competitiveness, innovation and economic growth. The question, then, is whether judicialization of regulatory reform tools such as IAs implies a market-liberal bias, whereas neutrality is expected from the judiciary.25

Of course, much depends on what the court will actually do. There is no market-liberal bias if the court simply verifies whether an impact assessment has been drawn up whenever this is a legal requirement. Also, the IA may give evidentiary evidence (or prove the lack thereof) useful for the proportionality test. Again, this remains a neutral operation. The danger of an ideological bias only pops up when the court uses the evidence in the IA to make its own assessment, on the basis of its own political preferences, instead of simply examining whether the lawmaker could base the assumptions and balances he made on the evidence provided by the IA.

On the other hand, legal review may broaden the focus on competitiveness, by also considering legal values and fundamental rights. This way, criticism that the practice of IAs leads to ‘quantification of the unquantifiable’26 can be addressed. Alemanno takes this further, asking ‘what IA has to offer courts’ rather than ‘what courts may offer to IA’.27

The crux lies in the convergence between the argumentative frameworks provided by the proportionality test, included in fundamental rights adjudication, on the one hand, and IAs on the other. With Stone Sweet and Matthews, we can conceive the proportionality test as an argumentative framework: a scheme that structures the reasoning behind decision-making.28 Generally, this scheme consists of four steps: 1) the measure must pursue a legitimate objective; 2) the measure must be suitable in view of this objective; even if it does not fully realize the objective it should at least have some causal relation; 3) the measure must be necessary; it must not curtail rights and legitimate interest more than needed given alternative options and 4) it must be proportional, even in the absence of a valid alternative option: the benefits must outweigh the costs. In turn, IAs typically identify the purpose of the law (step 1), the necessity of the measure (step 2), alternative options for the proposed measure including the zero option (step 3) as well as a balance of costs and benefits (step 4). Sometimes IAs are criticized for ignoring one of these steps. For example, the OECD, while praising France for its pioneering impact studies system, also points out some weaknesses, and recommends to draw attention to the option of maintaining the status quo as an alternative for the proposed measure, to summarize the main conclusions to enable easy

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26 A. Meuwese and S. van Voorst, supra note 2, at p. 23, with further references.
comparison of the various options, and to clearly pose the question of whether the measure is actually needed. However, if the IA is well-structured and meticulously executed, it provides all the necessary information to perform the proportionality test. A well-developed IA therefore protects legislative acts against invalidation by the court, whereas an underdeveloped IA suggests that the lawmaker has not sufficiently weighed costs and benefits or examined alternative options. The argument for including IAs (indirectly) in legal oversight procedures is that IAs provide judges with important input to assess whether a measure was appropriate or proportional.

3. Efficiency: the over-judicialization difficulty

The European Commission has expressly rejected the judicialization of regulatory tools, and consultations in particular, for fear that it would create ‘excessive rigidity and risk slowing the adoption of particular policies’. In literature, this is called the ‘over-judicialization’ difficulty, which makes the regulatory process contentious, inefficient and costly, as judicial conflicts may saturate rule formation and enforcements.

The sharpest criticism has been made with relation to judicial review of the US notice-and-comment-rulemaking for administrative agencies, which allegedly turned the procedure into a ‘burdensome, sclerotic process’, leading to the ossification of regulatory reform. Opponents point to mainly two effects of judicial review. First, courts have turned the APA’s requirement to adopt ‘a concise general statement of their basis and purpose’ after having given interested persons the opportunity to submit statements, into a duty to respond to ‘significant’ comments, prompting agencies to respond to all comments as no criteria are given to predict which comments court will consider ‘significant’. Second, where courts have the mandate to review agency rules for ‘arbitrariness’, this has turned into a procedural rationality review, requiring agencies to ‘examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made’.

The Supreme Court, however, specified in the same judgment that courts are not to substitute their own judgment for that of the agency, but should only invalidate rules if the agency failed to ‘examine the relevant data and articulate a satisfactory explanation’ with no ‘clear error of judgment’. Courts are nonetheless criticized for engaging in ‘a painstaking (one might say picky) review of the evidence, finding fault with the agency’s lack of explanation for inconsistencies in some scientific evidence’. Especially district courts have the tendency to put down rigid, costly and time-consuming constraints, for example by requiring agencies not only to use the available data, but to also collect additional data. As a result, agencies are said to be burdened to the extent that it takes them several years to create a ‘significant,

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30 A. Alemanno, *supra* note 27.


34 5 U.S. Code § 553 (c).

35 Shapiro and Murphy, *supra* note 33, at p. 14.


38 Shapiro and Murphy, *supra* note 33, at p. 15.

controversial’ rule.\textsuperscript{40} The fact that courts sometimes demand agencies to collect new data, is considered the major cause of distress.\textsuperscript{41} Instead, it was proposed that courts should, in principle, restrict to the rule that the rule-maker should rely on the available data.\textsuperscript{42}

There is discord as to the correctness of these statements.\textsuperscript{43} In any case, the prediction that these standards would turn out ‘insurmountable’ impediments leading to a ‘regulatory catastrophe’\textsuperscript{44} did not come true. On the contrary, figures presenting the most important rules, and graphs showing the evolution in the total pages of the Code of Federal Regulations, show an increase in the number of regulations.\textsuperscript{45} Moreover, although opponents put all the blame on courts, in reality Congress and Presidential rules have added to the complexity of agency rulemaking by imposing the preparation of risk assessments and cost-benefit analyses, for example environmental impact statements, business impact assessments, or broader regulatory IAs for major decisions.\textsuperscript{46} Finally, judicial review of agency action in the US is not always consistent, with a more deferential approach on one end of the spectrum, and the rigorous ‘hard look’ approach on the other.\textsuperscript{47}

Nonetheless, the length of the statements have been measured and turned out to be ‘concise’ only for the most routine rules. In most cases, the number of pages in the preamble, encompassing responses to all comments submitted, outweigh by far the length of the actual regulation.\textsuperscript{48} Also, studies have pointed out that the standards set by courts have kept agencies from enacting beneficial regulations in particular cases.\textsuperscript{49} So, assuming that the US experience gives evidence of the over-judicialization difficulty, the question is whether judicial review of IAs in Europe is likely to lead to ossification of the rulemaking process.

Judicialization may, on the other hand, also improve regulatory reform. Courts have been important in the development of US policy on risk and cost-benefit-analysis.\textsuperscript{50} Especially where rational lawmaking has not yet developed into an administrative culture, legal enforcement of basic steps – such as carrying out an IA in the first place – may help to change that culture over time.

4. The competency problem

Judges are said to have only limited capacity to judge the quality of administrative procedures within the regulatory process in general, and IAs in particular.\textsuperscript{51} Other professions than lawyers are better placed to assess the evidence-based quality of the regulatory process, such as administrative oversight bodies, nested within the internal administrative decision-making process.

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\textsuperscript{40} Shapiro and Murphy, \textit{supra} note 33, at p. 15.
\textsuperscript{41} Seidenfeld, \textit{supra} note 39, at p. 522.
\textsuperscript{42} Seidenfeld, \textit{supra} note 39, at p. 524.
\textsuperscript{45} See the data presented at the website of the Regulatory Studies Center, \url{https://regulatorystudies.columbian.gwu.edu/reg-stats/#Average%20Length%20of%20Review%20for%20Regulations}.
\textsuperscript{46} Seidenfeld, \textit{supra} note 39, at p. 485.
\textsuperscript{47} Anderson, Chirba-Martin \textit{et al.}, \textit{supra} note 43, at p. 113.
\textsuperscript{49} See the studies referred to in Seidenfeld, \textit{supra} note 39, at p. 487, fn 25.
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Judges are, indeed, more familiar with legal analysis rather than economic assessment methods. Of course, dealing with IAs might become an element in the legal training of judges, but even then, they cannot be expected to meticulously judge the quality of IAs. The question, then, is how deferential courts are with regard to the quality of the IA. Only in specific cases the need will rise to judge the quality of the IA as such. Here, they can take a deferential approach, and only interfere when the assessment is clearly deficient. For this, courts may rely on the judgment of independent experts, or on methodological principles and criteria that may form part of the regulatory reform tools.  

IV. Judicial evidence-based review in Europe: an empirical test

1. The data: an overview of case law

The theoretical debate, as sketched above, is based mainly on hypotheses, expectations of what courts will do and how legislatures will react, and on the basis of the US experience with agency regulations. In this section, we give an overview of how courts in Europe behave in fact when confronted with parliamentary acts, or with EU Acts approved by the EU Institutions.

Here, we can differentiate between two judicial mechanisms:

1) Process review, where an Act is challenged because no IA was conducted, or the IA that was carried out is deemed defective;

2) Procedural rationality review, where the Act is challenged for failing a substantive check which includes the duty to legislate on the basis of evidence (e.g. the proportionality or the subsidiarity test).

A. Process review

Formal process review implies that the Court invalidates an Act for the fact that in the preparatory phase, a procedural requirement – in this case, the duty to carry out an impact assessment – has not been complied with. This implies a legal ground to impose such duty and the power of the Court to review act against this provision. In most legal systems, however, the duty to carry out an impact assessment is inserted in guidelines only, or, at most, in royal decrees or statutes. While scholars have argued that the duty to carry out IAs laid down in soft law can be self-binding, there is no case law to this effect. Instead, the ECJ holds that the European Parliament and the Council are not bound by the Institutional Agreement to carry out their own IAs in the case of an amendment. Most interesting, therefor, are the French system as well as the EU to the extent that the duty to conduct an impact assessment is considered to have constitutional value.

• The French model

A duty to conduct an impact assessment is laid down in Article 8 of the 2009 Institutional Act and is indirectly given constitutional value, as according to Art. 39 § 4 of the Constitution, government bills may not be included on the agenda if the Conference of Presidents of the first House declares that the rules determined by the Institutional Act have been ignored. The Constitutional Council has the

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54 Case C-343/09, Afton Chemical, 8 July 2010, para 30-40; Case C-, Pillbox 38 (UK) Ltd, 4 May 2016, para 64-66.

55 Loi Organique n° 2009-403.
power of *ex ante* review, by way of two mechanisms. According to Art. 39 § 4 of the Constitution, in the case of disagreement between the Conference and the Government of whether the rules of the Institutional Act have been ignored, the matter may be referred to the Constitutional Council. According to Art. 61 of the Constitution, Institutional Acts are referred to the Constitutional Council to rule on their conformity with the constitution; other Acts of Parliament may also be referred to the Council before their promulgation on request of the President of the Republic, the Prime Minister, the President of the National Assembly or the Senate, or sixty members of the National Assembly or the Senate.

Apart from that, the Constitutional Council can review Parliamentary Acts *ex post* on the preliminary request of the Council of State or the Court of Cassation, if it is claimed that a legislative provision infringes the rights and freedoms guaranteed by the Constitution. This legal ground does not differ from the grounds on which any constitutional court may review Parliamentary Acts. The question, then, is whether the obligation to obey the Institutional Act constitutionalizes the duty to conduct an impact assessment - and if so, whether this duty for the Government can be considered a constitutional right for persons. Until now, impact assessments have not been considered by the Constitutional Council through its *ex post* review power.

By contrast, the duty to carry out an impact assessment was considered by the Council by way of its *ex ante* review. The website of the Constitutional Council points to nine cases. In one of them, the Institutional Act which lays down the duty to carry out an IA was scrutinized by the Council. This was a successful challenge, as the Council invalidated part of the duty, in so far as the law required the mentioning of specific details concerning the executive measures, which was considered a violation of the separation of powers. In the other eight judgments the Council checked the observance of the Institutional Act, and none of the challenges was successful.

Only one of these judgments is based upon Art 39 of the Constitution. Here, the Council established that the draft law was accompanied by an IA and that the IA contained the data required by the Institutional Act as well as the reasons for choosing the option presented by the bill and the foreseeable consequences. To the claim that the IA should also give data on the evolution of the number of public offices, the Council replied that this was not necessary, because the Government did not mention the alteration of this number as one of its goals. Also, the Council did not agree that the IA should give more information on the consultations that were held, as it did not find evidence that consultations had taken place under conditions that should have been mentioned in the IA. Hence, it did not examine whether consultations should have taken place, but merely established that if they did not take place, they must not be mentioned in the IA.

This was the most intensive review of IAs: the other seven judgments, all based on Art. 61 of the Constitution, are even more formal in nature.

In the first judgment, the MPs that requested the judgment claimed that the conference of presidents had not gathered within ten days and therefore could not establish whether the impact assessment had been authentic. The Council, however, stated that the conference did gather within ten days.

In five other judgments, the absence of an IA was invoked, but the Council replied that the case concerned a provision that was introduced by way of an amendment, to which the duty to carry out

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57 2014-12 FNR, 1er juillet 2014, cons. 5 à 7, JORF du 3 juillet 2014 page 11023, texte n° 100
an impact assessment did not apply. In one of these judgments, the applicants complained that the number of amendments was so high that it was apparently used by the Government to avoid the duties laid down in the Institutional Act, such as the carrying out of an IA, as well as the duty to consult the Council of State or to deliberate in the Council of Ministers. The Council, however, was not willing to examine the possible improper use of the right of amendment.

In one of these judgments, the applicants also complained that the IA was incomplete when it was sent to the Council of State for advice. This means that the IA was partly carried out after the bill was drafted, which undermines the purpose of the IA as an instrument to guide the decision making process. The Constitutional Council, however, held that the Institutional Act only required that the IA is completed when it is submitted to Parliament and therefore there was no breach of the formal requirements.

In two judgments, the applicants complained that the IA was deficient, because it contained material errors and did not sufficiently examine the social, economic or financial impact of the bill.

The first case preceded the Institutional Act of 2009 which laid down the duty to carry out an IA. Here, the Council simply stated that an IA serves to inform Parliament and that possible imperfections did not impact on the regularity of the eventual law. In the second case, the Council avoided having to assess the quality of the IA by pointing to the fact that the Conference of Presidents had ten days at its disposal to consider compliance with the duty to carry out an IA and that the IA had not been disputed during that time. This puts a heavy weight on the Conference of Presidents as regulatory watchdog: if the IA is not disputed at this moment, it cannot be challenged before Court anymore.

- Formal process review: the EU

A legal duty to carry out impact assessments is explicitly laid down in Art. 5 of the Protocol N° 2 on the Application of the Principles of Subsidiarity and Proportionality. According to this Article, draft European legislative act should contain a detailed statement making it possible to appraise compliance with the proportionality and subsidiarity principles. This statement should contain some assessment of the proposal’s financial impact and must substantiate the reasons for concluding that a Union objective can be better achieved at Union level by qualitative and, wherever possible, quantitative indicators. It should also take account of the need to minimize financial and administrative burdens falling upon the Union, national, regional or local authorities, economic operators and citizens and to commensurate them with the objective to be achieved.

60 2015-715 DC, 5 août 2015, cons. 2 à 7, JORF n°0181 du 7 août 2015, p. 13616, texte n° 2 ; 2016-739 DC, 17 novembre 2016, paragr. 2, 4 et 6, JORF n°0269 du 19 novembre 2016 texte n° 4.

The Article was invoked several times to challenge the absence or deficiency of an impact assessment. The ECJ confirmed that it must verify compliance with not only the substantive, but also the procedural safeguards provided for by Protocol N° 2.64

In *Philip Morris* and in *Poland v the EP and the Council*, the ECJ pointed out that the Commission’s proposal and its impact assessment included sufficient information ‘showing clearly and unequivocally the advantages of taking action at EU level’. 65 This had already been examined under the substantive proportionality and subsidiarity tests. In Estonia, the Court also clarified that the impact assessment should not be so detailed as to examine the impact of any individual provision or on any particular Member State.66

In *Afton Chemicals* and *Pillbox 38* it was claimed that the Directive at stake was invalid because of the absence of an IA to support the measure that was adopted. In these cases, the legislature had chosen another measure than the one proposed by the Commission; hence the measure had not been examined in the IA. The Court pointed out that an impact assessment is not binding on either the Parliament or the Council, allowing them to adopt a different measure than the ones examined in the IA.67 The Court did not require them to carry out their own IA, but was satisfied that the available scientific evidence was taken into account and that a number of consultations and meetings were organized at a late stage of the decision making process.

**B. Procedural rationality review**

The rise of procedural rationality review – also called semi-procedural review – in the case law of Constitutional and European Courts is a topic of debate in recent literature.

Procedural rationality review is part of a substantive check – usually a proportionally check – where the Court takes into consideration the quality of the decision-making procedure at the legislative (or administrative and judicial) stage as a decisive factor for assessing whether government interference was justified. It comes into play when the Court is unable to substantively assess the merits of a case, for example if it has to leave a wide margin of appreciation for what is essentially a political exercise, such as the balancing of economic interests and environmental concerns.68 In that case, the Court, instead of second-guessing the appropriateness of policy choices, reduces its scrutiny to the question of whether the lawmaker based the balancing exercise upon an informed and inclusive discussion. It is also used when government interference rests upon an assumption for which evidence is required.

The most explicit statement in that regard was the European Court of Human Right’s decision in *Hatton v the UK*. The Grand Chamber stated that ‘a governmental decision-making process concerning complex issues of environmental and economic policy such as in the present case must necessarily involve appropriate investigations and studies in order to allow them to strike a fair balance between the various conflicting interests at stake.*69

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64 Case C-547/14, *Philip Morris Brands and Others*, 4 May 2016, para 217; Case C-358/14, *Republic of Poland v European Parliament and the Council of the EU*, para 113.

65 Case C-547/14, *Philip Morris Brands and Others*, 4 May 2016, para 226; Case C-358/14, *Republic of Poland v the European Parliament and the Council of the EU*, para 123.


68 Exceptionally – but open to criticism – the ECtHR relies on procedural rationality review despite a narrow margin of appreciation, see Grand Chamber, *Animal Defenders International v. the United Kingdom*, [App. No 48876/08], 22 April 2013.

Courts mostly turn to procedural rationality review when they carry out a proportionally check as part of a fundamental rights test or a subsidiarity test. The ECJ may turn to the IA to find evidence for the Commission’s argument that the objectives of the proposed action cannot be sufficiently achieved by the Member States. In these cases, carrying out an impact assessment is not a formal requirement. What the court is interested in, is whether in the course of the procedure the lawmaker sought all the information available through consultations, studies, etc. An impact assessment is only one of various options to find evidence for the rationality of the decision making process. It may protect the law against invalidation, but, if deficient, this may be considered an element to find the law disproportional.

While procedural rationality review has become a topical subject of scholarly debate, it is a rather uncommon phenomenon in the practice of courts. Specific data are available for the Belgian Constitutional Court, where all decisions, until 31 December 2015, have been coded in a database. The data show that the court only rarely turns to procedural rationality review. In fact, the Court refers to evidence – studies, reports, etc – in only 2% of the cases. Such data are not available for other courts, but we can expect similar results. Moreover, in most cases, procedural rationality review is used to uphold the measure. In the Belgian Constitutional Court, scientific evidence was referred to in only 16 judgments to sustain invalidation of the law – i.e. 0.5% of all judgments between 1985 and 2015. The number is even negligible if we focus on judgments in which regulatory impact assessments are taken into consideration.

In this section, the case law of the European Courts is further examined. The European Court of Human Rights is examined because, with the German Constitutional Court, it is a forerunner of procedural rationality review, and, moreover, may influence national courts to adopt similar approaches. The European Court of Justice is also examined because here, most reference is made to impact assessments in particular.

- **The European Court of Human Rights**

In the case law of the European Court of Human Rights, the only judgments of some significance that mention IAs, concern the environmental impact assessment foregoing the issuing of concrete permits. Regulatory impact assessments were mentioned in only two cases. In *Dubska and Krejzova*, the applicants complained that a Decree infringed the compulsory procedure for the adoption of secondary legislation, since no regulatory impact assessment had been performed. The Grand Chamber, however, did not go into the issue, but was satisfied that the Act clearly laid down the requirements for health professionals to assist with a planned home birth and was therefore in compliance.

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71 This was part of a research project funded by the FWO Flanders, promoters P Popelier and J Beyers, and carried out by J De Jaegere.


73 And 28% of the judgments in which scientific evidence plays a substantial role. See Popelier and De Jaegere, supra note 72.

more judgments, however, can be identified in which the Court looks for scientific evidence to underpin the proportionality of legislative interference.

Here as well, procedural rationality review usually leads to the verdict that the law is proportional. In Hatton, the Court had initially concluded that ‘in the absence of any serious attempt to evaluate the extent or impact of the interferences with the applicants’ sleep patterns, and generally in the absence of a prior specific and complete study with the aim of finding the least onerous solution as regards human rights’, the government had not struck the right balance in weighing the interferences against the economic interest of the country.78 The Grand Chamber reversed this decision, emphasizing that it is not required to decide on the basis of ‘comprehensive and measurable data in relation to each and every aspect of the matter to be decided’.79

Only rarely does the lack of evidence lead to the conclusion that the law is not proportional. In most cases, the Government had justified the law with reference to legislative assumptions for which the Court did not find any evidence. For instance, in Lecarpentier, the measure at stake was justified for the purpose of saving the financial balance of the banking system and the economic activity in general, but the Court did not find any element to prove the presence of such danger.80 In Konstantin Markin, concerning the legislation that allowed servicewomen, but not servicemen, to take parental leave, the Government stated that allowing servicemen to take three years’ parental leave would affect the operational effectiveness of the army. The Court noted that ‘there is no indication that any expert study or statistical research was ever made by the Russian authorities to evaluate the number of servicemen who would be in a position to take three years’ parental leave at any given time and would be willing to do so, and to assess how this would affect the operational effectiveness of the army’.81 In Kiyutin a restriction on temporary residence of HIV-infected foreign nationals was at stake, to ensure the protection of public health. While third parties had submitted evidence to an existing consensus amongst experts and international bodies active in the field of public health, that such travel restrictions were ineffective and could not be justified by reference to public health concerns, the Court noted that the Government ‘did not adduce any expert opinions or scientific analysis that would be capable of gainsaying the unanimous view of international experts’.82

In these cases, legislation was enacted based on assumptions that lacked any evidentiary foundation. By contrast, in Smith and Grady, the government did submit evidence to the assumption that admitting homosexuals to the armed forces would have a significant and negative effect on the

75 Grand Chamber, Dubska and Krejzova v the Czech Republic, [App Nos. 28859/11 and 28473/12], 15 November 2016, paras 85, 171.
77 Para 139.
81 Konstantin Markin v Russia [App No 30078/06] 22 March 2012, para 144.
morale of armed forces’ personnel and, in turn, on the fighting power and the operational effectiveness of the armed forces. The Court, however, expressed doubts as to the value of the surveys and studies carried out. According to the Court, the evidence produced was manifestly biased and, above all, merely represented a negative attitude of a heterosexual majority against a homosexual minority but did in no way substantiate the alleged damage to the morale and operational effectiveness that any change in policy would entail. Hence, the decisive element was, again, that no evidence was given to prove that admitting homosexuals would actually reduce the fighting power and operational effectiveness of the armed forces.

- The Court of Justice

The Court of Justice of the European Union deserves specific attention, because impact assessments are more often looked at than is the case in other courts. Nonetheless, while the spotlights on well-known cases such as Vodafone or Spain v Council are widely commented upon, they may give a distorted picture because, in the end, the number of relevant cases is limited to hardly two handfuls.

In these cases, the Court leaves broad discretion to the European legislature if choices have to be made of an economic, political or social nature which require complex evaluations, but underlines that these choices should nevertheless rely on objective criteria. The legislature’s broad discretion, however, also applies, ‘to some extent’, to finding of the basic facts. Hence, the fact that an impact assessment has been carried out in which various options are examined, is an important factor to conclude that a given measure is proportional. Furthermore, where the European legislature has to assess the future effects of legislation that cannot accurately be foreseen, its assessment is open to criticism only ‘if it appears manifestly incorrect in the light of the information available to it at the time of the adoption of the legislation in question’.

However, according to the Court, discretion ‘presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate’. The Court will interfere if the institutions are not able to ‘produce and set out clear and unequivocally the basic facts which had to be taken into account as the basis of the contested measures of the act and on which the exercise of their discretion depended’. Again, this leads only very exceptionally to the invalidation of the Act. In Spain v Council the ECJ held that the Commission calculated the foreseeable profitability of cotton growing under the new support scheme to determine the amount of the specific aid for cotton, but did not include two relevant factors, namely the labour costs linked to cotton growing and the viability of the ginning undertakings. Further, in Volker und Markus Schecke, the impact assessment as such is not mentioned, but the Court reproaches the Council and the Commission for not having examined alternative options for publishing information on the

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83 Smith and Grady [App ] No para 95.
84 Paras 97-99.
85 Case 58/08 Vodafone, [2010] ECR I-4999, paras 54 and 68; Case C-547/14, Philip Morris Brands and Others, 4 May 2016.
88 Jippes, para 84, Case C-310/04 Spain v Council [2006] ECLI-521, para 120
90 Case C-310/04 Spain v Council [2006] ECLI-521, para 123.
91 Case C-310/04 Spain v Council [2006] ECLI-521, para 133.
beneficiaries of agricultural aid causing less interference with those beneficiaries’ right to respect for their private life and the protection of their personal data.92

2. Evaluation: judicial review of IAs – valuable or burdensome?

We now turn again to the arguments put forward in the theoretical debate, to assess whether the expectations of either the opponents or the advocates of judicial review have proved correct or not.

a) Political primacy

The first set of arguments was based on political primacy. According to opponents, judicial review undermines political primacy by substituting legitimate political decision making for scientific reasoning. According to advocates, judicial review reinforces the legitimacy of political decision making and leads to more careful and rational lawmaking.

From the evidence produced by the case law of France and the ECJ, we can conclude that formal process review does not meet the expectations by either opponents or advocates of judicial review. In France, the judicial review of the duty to carry out an IA is interpreted as a formal exercise. Observance of this duty does not inquire into the purpose of impact assessments, nor does the Council wish to engage with the quality of the IA that was conducted. While this type of judicial review may secure formal compliance with procedural requirements, it is satisfied with a ticking of the box. In the EU as well, the formal process review does not amount to much. This type of review does not threaten to undermine the primacy of policy making, nor is it likely to impact the lawmaking procedure or reinforce its legitimacy.

This is different when it comes to procedural rationality review, conducted mainly under the proportionality and subsidiarity test.

The case law of the European Court of Human Right already showed that procedural rationality review, by requiring some evidentiary basis for legislative interference, aims at shaping policy making. Given the fact that legislation is invalidated on this ground only in exceptional cases and mainly when the Government is not able to produce any evidence to substantiate the assumption on the basis of which interference with a fundamental right was justified, the judicial interference, however, remains limited and can hardly be said to replace political decision making by scientific reasoning.

The same applies to the ECJ. While the Court requires some evidentiary basis, it is satisfied when the preparatory documents, and the IA in particular, show that the legislature has exercised due care in weighing the options and interests on the basis of available information. The Court seems more rigid with regard to the examination of alternative options where fundamental rights are at stake. The review of the requirement to rely on objective criteria seems stricter compared to the case law of the European Court of human rights. This may be due to the fact that EU regulations are of a more technical nature and therefore more demanding of scientific evidence. Also, the fact that IAs are available, may pull the court into a more intensive investigation. In the end, however, the Court’s examination tends to support the European legislation. Consequently, the more detailed the Courts’ investigation, the more it legitimizes the Act at stake.

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92 Joined Cases C-92 and 93/09 Volker und Markus Schecke GbR, judgment of 9 November 2010, para 77, 83.
b) The market-liberal bias argument

Where the Court’s review is confined to process review, content is hardly an issue and no ideological bias is discernible. This is different where IAs are used in proportionality or subsidiarity tests.

The Court of Justice leaves broad discretion to the EU legislature, examining mainly whether the legislature’s choices rely on objective criteria, taking into consideration the facts and information available at the time of adoption of the legislation, and criticizing the legislature’s assessment only if it appears manifestly incorrect. If the outcome reveals some market-liberal bias, then this is simply the legal and political context in which the Court is functioning.

By contrast, the case law does show that procedural rational review can broaden that scope by bringing in a fundamental rights perspective. This is, not surprisingly, the case for the European Court of Human Rights, where it looks for scientific evidence to underpin the proportionality of legislative interference. This way, the Court can prick through assumptions that are often based on social or political prejudices but have no factual basis. Hence, instead of reinforcing a market-liberal bias, procedural rationality review helps to steer away from ideological biases. This function is less apparent in the case law of the ECJ, for whom the protection of fundamental rights is not the core function. Nevertheless, procedural rationality review shows added value here as well. For example, in Volker und Markus Schecke the ECJ incited the EU legislature to examine alternative options for its interference, taking into consideration the right to respect for privacy and the protection of personal data.

c) The over-judicialization difficulty

We have no evidence of whether process or procedural rationality review by courts has impacted on the regulatory process in the EU or in specific countries. We can observe, however, a fairly deferential approach by European courts, which undermines the argument of over-judicialization. At the EU level, the fundamental rights test was included in the IA following the ECJ case law, but there is no evidence that this has substantially overburdened the administration. Also, the cases where the decision making process at large and the impact assessment in particular is under dispute, are rare, and the courts are usually satisfied with the work that has been carried out on the basis of the available data, without imposing further steps to be taken. While courts do require, to some extent, that legislation is evidence-based, the legislature is allowed much discretion in the choice of instruments and methodology.

Judicial review, then, does not risk to lead to ossification of the rulemaking process. There is, however, also no proof that it helps to develop an administrative culture of rational, evidence-based law-making. In the EU, the Commission was already convinced of the importance of a better law making policy. Given the basic deferential stance of courts, we can assume that in an individual state, courts will be extra cautious where better lawmaking is not part of an institutional and political context. Where the EU and the European Court might give an impetus to, respectively, member states and contracting parties, this might be restricted to matters with an exclusively EU or fundamental rights-dimension.
d) The competency problem

The competency problem may explain why in many legal systems, courts pay little attention to impact assessments. Where they do look into IAs and other material produced in the lawmaking process, they usually exercise restraint when it comes to assessing the quality of such studies. The overview of case law reveals that courts only interfere in exceptional circumstances, when the studies suffered obvious deficiencies.

Only rarely do courts take this further. An example is the Hartz IV decision of the German Constitutional Court, where it obliged the legislature to disclose the methods and calculations on which certain measures were based, such as the substance minimum. It held that a failure to adequately disclose such methods and calculations had as a result that the subsistence minimum was not in compliance with the Constitution, according to which every needy person has a right to the material conditions indispensable for his or her physical existence and for a minimum participation in social, cultural and political life. This was criticized in literature, because the amount determined by the legislature did not seem to be evidently insufficient, taking into account additional benefits and free health care, and compared to substance minimum rates in other countries.

This criticism implies that courts should use evidence to examine the proportionality of legislation where this is under dispute, but not to invalidate legislation the outcome of which does not seem to violate the constitution or a treaty.

Conclusion

Should we fear or embrace the judicialization of regulatory tools in general and impact assessments in particular?

An overview of jurisprudential practice in Europe shows that we should not overestimate the impact of judicial review. Where primary legislation is at stake, courts take a deferential stance, protecting the legislature against technocratic regulatory capture or ossification of the decision making procedure. On the other hand, expectations that judicial review will lead to more rational and careful lawmaking, seem over-optimistic. This is certainly the case where judicial review is confined to strict formal process review. Overall, however, the scale turns in favor of procedural rationality review. This type of review leaves broad deference to the legislature as to procedural steps and methods, but makes way for a fundamental rights perspective and interferes when political rationality or ideological bias leads to arbitrary interference.

93 Joined Cases 1 BvL 1/09, 1 BvL 3/09, 1 BvL 4/09 § 144.
94 Messerschmidt, supra footnote 25.