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Putting evidence-based law making to the test: judicial review of legislative rationality

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ABSTRACT

Both at the European and at the Member State level, evidence-based law making is on the rise. So far, the attention has mostly gone to methods of ex ante evaluation used by the legislature. In this article, we argue that more attention should be paid to the role of courts as regulatory watchdogs. The CJEU seems to move in this direction by increasingly conducting a procedural (proportionality) review of legislation. However, the CJEU does not yet scrutinise the underlying data or the scientific evidence on which consultations, impact assessments and other forms of ex ante evaluation rest. This means that when these evaluations are based on poor quality data, this will also affect the CJEU's judgement. For Dutch courts, the situation is different. They are so far unwilling to include ex ante evaluations or empirical data in a proportionality review of legislation, although the Advisory Division of the Council of State emphasises the principles of subsidiarity and proportionality in its policy-analytical review of draft legislation. This raises the question: why do courts avoid assessing the reliability of (scientific) evidence used by legislators and regulators? Here they might learn something from the US, where the Supreme Court developed its Daubert doctrine in order to guide courts in filtering out 'junk science' from the law-making process.

KEYWORDS Evidence-based; proportionality test; Daubert

1. Introduction

Both in the legislative policy of the EU and its member states, evidence-based law- and policy-making are on the rise. The idea of 'evidence-based law-making' is relatively new, but draws on an extensive body of 'evidence-based' areas, such as evidence-based medicine, evidence-based policy, evidence-based management and so on.¹ There has been a spillover from

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¹H. Hamann, *Evidenzbasierte Jurisprudenz: Methoden empirischer Forschung und ihr Erkenntniswert für das Recht am Beispiel des Gesellschaftsrechts* (Mohr Siebeck 2014).

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these areas to the field of legislation, where we have witnessed a general shift from codification of existing customs and morals to modification of human behaviour.² Antokolskaia describes the move towards evidence-based legislation as: 'the legislator in his choices for legislative interventions takes a rational and focused approach and does not let himself be guided by just political and ideological reasoning, but also by relevant results of scientific inquiry assessing the (expected) effectiveness of those interventions.'³

Much has been written about the virtues of evidence-based legislation.⁴ However, sceptics have argued that one should not overestimate the advantages of an evidence-based approach because policy makers and politicians are not always willing to take scientific insights into account. Putting too much emphasis on the need to underpin legislative drafts with empirical data and scientific evidence could even produce counter-productive effects and turn evidence-based policy-making into policy-based evidence-making.⁵ Taking a critical look at current practices, one may wonder if this is not already going on. Impact assessments, for example, rarely lead to a choice for alternatives to legislation, consultations seldom result in significant changes to legislative drafts and the results of legislative experiments are sometimes simply neglected. In other words, how relevant and reliable are existing procedures that should make our laws and regulations more evidence-based?

2. How evidence-based is evidence-based law: and what is the role of courts?

Regulatory oversight is still a weak spot in the regulatory policies of the EU and probably in most of its member states. At the EU level, Directorate Generals (DGs) are primarily responsible for carrying out impact assessments and the supervision by institutions, such as Regulatory Scrutiny Boards, Audit Offices and Ombudsmen, is relatively weak. These bodies are usually not capable of blocking bad legislative drafts from passing through. So far, little

²T. Koopmans, 'De rol van de wetgever' in Herman Schoordijk, W. van der Grinten, C. Polak and G. Langemeijer (eds.), *Honderd jaar rechtsleven: de Nederlandse Juristen-Vereniging 1870–1970* (Tjeenk Willink 1970) 221–235.

³M. Antokolskaia, 'Van politiek gestuurde wetgeving naar evidence-based wetgeving: Nog een lange weg te gaan' in W. van Boom, I. Giesen and A. Verheij (eds.), *Capita Civilogie. Handboek Empirie en Privaatrecht* (Boom Juridische uitgevers 2013) 174. R. van Gestel, 'Evidence-based Lawmaking and the Quality of Legislation: Regulatory Impact Assessments in the European Union and the Netherlands' in H. Schäffer and J. Iliopoulos-Strangas (eds.), *State Modernization in Europe* (Berliner Wissenschaftsverlag 2007) 141 defines evidence-based legislation as: 'laws and policy initiatives are to be supported by research evidence and policies are preferably introduced on a trial and error basis. Implementation should only be considered on a larger scale after an evaluation of experiments or pilots have taken place.'

⁴P. Schwintowski, '... denn sie wissen nicht, was sie tun! - Warum Politik und Gesetzgebung so oft irren: Ein Plädoyer für die Neue Analytische Regelungswissenschaft' (Nomos 2014) and A. Seidman and R. Seidman, 'ILTAM: Drafting Evidence-based Legislation for Democratic Social Change' [2009] *Boston University Law Review* 448–485.

⁵House of Commons Science and Technology Committee, *Scientific Advice, Risk and Evidence Based Policy Making, Seventh Report of Session 2005–2006* (House of Commons, London November 2006) 47.

attention has gone to the role of courts as regulatory watchdogs.⁶ In a way, this is understandable because each branch of government has its own constitutional role to play, which explains why courts are reluctant to invade the legislative domain.⁷

Nevertheless, as Lenaerts has observed,⁸ cases such as *Vodafone*, *Volker und Markus Schecke*, and *Test-Achats* are judgments revealing that the CJEU is willing to follow an approach that focuses on improving the evidence-base of the decision-making process of EU institutions, rather than on second-guessing their substantive findings. In these cases, the CJEU conducts a procedural review, which tests to what extent EU political institutions have followed the procedural steps mandated by the authors of the Treaties and by the different EU institutions themselves (e.g. think of impact assessment (IA) and consultation guidelines developed by the Commission). Such a review may prevent the CJEU from entering the realm of politics. Unfortunately, however, it cannot capture the substantive truth-value or validity of the empirical basis on which laws and regulations rest. Hence, a procedural test may either be under-inclusive (e.g. legislation is prepared according to all the guidelines for drafting, consultation, impact assessment but the content of the rules still has major flaws) or over-inclusive (e.g. passing a multitude of tests becomes a goal in itself and distracts the attention from achieving the goals of the legislature).

3. Research problem and order of the argument

There are some important differences between how the CJEU scrutinises legislation and how the Dutch highest courts, and especially the Council of State, do this. Article 120 of the Dutch constitution, for example, prohibits courts from testing the constitutionality of statutes.⁹

A first step in this paper is to compare how the CJEU and Dutch courts apply a proportionality test. In the Netherlands, there is increasing criticism that the case law of the Council of State is biased towards protecting the government against citizens who have legitimate doubts about the validity of laws and regulations.¹⁰ Although the intensity of the proportionality review differs,

⁶For an exception see: P. Popelier, 'Preliminary Comments on the Role of Courts as Regulatory Watchdogs' 2012 *Legisprudence* 257–270.

⁷At least that is the idea behind the *Trias Politica* doctrine derived from the work of Montesquieu. To what extent this doctrine is still useful as a model to understand the relationships between the principle law-making powers in modern administrative states is up for debate. See B. Ackerman, 'Good-bye Montesquieu' in S. Rose-Ackerman and P. Lindseth, *Comparative Administrative Law* (Edward Elgar 2010) 128–133 and B. Ackerman, 'The New Separation of Powers' 2000 113 *Harvard Law Review* 633.

⁸K. Lenaerts, 'The European Court of Justice and Process-Oriented Review' [2012] *Yearbook of European Law* 3–16.

⁹Article 120 reads: 'The constitutionality of Acts of Parliament and treaties shall not be reviewed by the courts.'

¹⁰Even the former chairman of the Administrative Jurisdiction Division of the Council of State and former Minister of Justice in the Netherlands, Ernst Hirsch Ballin, now criticises the marginal review that the court applies when deciding over the quality of legislation. See E. Hirsch Ballin, 'Dynamiek in de

both courts seem to share a dilemma,¹¹ which forms the principle background of our contribution, namely:

To what extent does a proportionality review of laws and regulations by the judiciary require that courts assess the methodological rigour of ex ante evaluations conducted during the preparation of laws and scrutinize the empirical data and scientific evidence used to underpin regulatory decisions?

In order to answer this question, we will summarise how the proportionality principle is explained in both legal systems. After that, we will explore the case law of the CJEU, the Dutch Supreme Court and Council of State looking for examples where a proportionality test was used to scrutinise laws or regulations. Are courts aware of the fact that the validity of the evidence on which laws and regulations rest may affect the quality of law making? After all, even if all the procedural steps prescribed by ex ante evaluation policies are followed, this does not imply that laws and regulations will reach their aim. Munday has even challenged the idea that courts should rely on regulatory impact assessments in the case of statutory interpretation. He believes impact assessments are politicised documents, which might undermine the quality of judicial decisions.¹² Should courts therefore not be more critical about the empirical data and scientific evidence that is used in the drafting of laws and regulations? If so, are courts capable of doing this?¹³ Perhaps the CJEU and Dutch courts could learn something here from the Dauber test, which was developed by the US Supreme Court to scrutinise the quality of expert witnesses and other kinds of scientific evidence. Therefore, we will list some possible advantages of applying such a test to a European context.

4. The review of legislative rationality in the Netherlands

4.1. Proportionality in the Dutch legislative context

In the Netherlands, subsidiarity and proportionality are important indicators for legislative quality.¹⁴ The subsidiarity principle requires that regulatory decisions should as much as possible be left to local authorities and non-

bestuursrechtspraak' in E. Hirsch Ballin, R. Ortlep and A. Tollenaar, *Rechtsontwikkeling door de bestuursrechter* (Boom Juridische uitgevers 2015) 9–58.

¹¹The dilemma has to do with the idea that a mere procedural review in which courts scrutinise the extent to which the legislature has taken its own procedural guidelines and ex ante evaluations into account may be relatively safe because it keeps courts away from policy decisions. On the other hand, plain procedural review might not suffice in case the evidence on which the legislature relies is flawed.

¹²R. Munday, 'In the Wake of 'Good Governance': Impact Assessments and the Politicisation of Statutory Interpretation' (2008) 71 *The Modern Law Review* 385–412.

¹³See for instance: *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 309 (1997): 'Congress has the capacity to investigate and analyze facts beyond anything the judiciary could match.'

¹⁴An extensive explanation of these (and other) quality indicators can be found in: Ministry of Justice, *Legislation in perspective*, The Hague 1991.

governmental organisations.¹⁵ The Dutch legislature prefers self-regulation to governmental regulation, whenever this is possible.¹⁶ Consequently, the guidelines for legislative drafting introduce a number of issues that should be taken into account before new laws are introduced. Instruction 7 of these guidelines determines that:

Before deciding to introduce a regulation, the following steps shall be taken: a. knowledge of the relevant facts and circumstances shall be acquired; b. the objectives being aimed at shall be defined in the most specific, accurate terms possible; c. it shall be investigated whether the objectives selected can be achieved using the capacity for self-regulation in the sector or sectors concerned or whether government intervention is required; d. if government intervention is necessary, it shall be investigated whether the objectives in view could be achieved by amending or making better use of existing instruments, or, if this proves impossible, what other options are available; e. the various options shall be compared and considered with care.¹⁷

Dutch legislators should refrain from direct intervention as much as possible and instead provide a general framework for self-regulation where possible. In practice, however, the explanation of why non-regulation or self-regulation has not been preferred over governmental regulation is often absent or weak.^{18,19} Although proportionality is usually mentioned in the same breath with subsidiarity, it has a different meaning. Proportionality depends on other norms because it can only function in relation to legislative or constitutional provisions that leave a certain margin of discretion. It requires a balancing of interests in which the composite weight of the disadvantages of a regulatory decision for the addressees may not outweigh the advantages to the general interest.²⁰

In order to determine whether a certain regulatory measure is proportionate, one needs to know the aims of the measure and the availability of different means to accomplish them. Without this, it is impossible to decide whether regulatory interventions are necessary and appropriate, let alone because a comparison between alternative measures would be impossible. Such a balancing of interests underlines the political nature of legislative drafting. Hence, if laws do not produce their intended effects, citizens must primarily look to the

¹⁵The principles of subsidiarity and proportionality as legislative quality indicators can be found in the Dutch Guidelines for legislative drafting. See: <http://wetten.overheid.nl/BWBR0005730/2011-05-11>.

¹⁶The ideas behind the Dutch emphasis on self-regulation are heavily influenced by the ideas of Niklas Luhmann and Gunter Teubner as can be witnessed in the Green paper: *Zicht op wetgeving*, Parliamentary Papers II, 1990–1991, 22008, nr 2.

¹⁷*Ibid.*, n 16.

¹⁸Instruction 212, under b, of the guidelines on legislative drafting requires that the necessity of regulatory intervention and the consideration of alternative modes of regulation are always presented in the explanatory memorandum of a proposed bill.

¹⁹R. van Gestel and M. Menting, 'Ex Ante Evaluation and Alternatives to Legislation: Going Dutch?' 2011 *Statute Law Review* 209–226.

²⁰A. de Moor-van Vugt, *Maten en gewichten: Het evenredigheidsbeginsel in Europees perspectief* (Kluwer 1995) 16.

government for action.²¹ This does not imply, though, that the judiciary has no role to play. However, in the Dutch context, this role is limited because of article 120 of the constitution. The core of that rule includes a prohibition on procedural testing,²² on substantive testing, as well as on the testing of preparatory actions.²³ In 1989, the Supreme Court ruled that the Dutch constitution even prohibits courts from testing a statutory provision in the light of fundamental principles of law.²⁴ The idea behind all this is to protect the primacy of parliament.²⁵

With regard to secondary legislation (e.g. Royal decrees and Ministerial regulations), the situation is different. Administrative courts are not allowed to review generally binding regulations,²⁶ but litigants may question the legality of an administrative order because of the unlawfulness of the underlying statutory provision.²⁷ Residual legal protection is provided by Dutch civil courts for which the Dutch Supreme Court set a standard in its landmark ruling *Landbouwwliegers*.²⁸ In this case, it decided that civil courts might review secondary legislation against the backdrop of general principles of law.²⁹

In *Landbouwwliegers*, aviation companies complained that new zoning requirements for spraying pesticides constituted a disproportionate limitation of their rights, especially now that the government refused to provide financial compensation for a 50 to 70% loss of return for the airlines. The Supreme Court, however, found that the consequences of the rules were not disproportionate in light of the unavoidable balancing of interest between the economic loss for the companies and the risks for the health and safety of the public.³⁰

4.2. Assessment of the proportionality of Dutch laws via the ECHR

The most important route towards a proportionality review of legislative decisions in the Netherlands runs via the European Convention on Human Rights (ECHR). First courts will need to decide whether a law or regulation

²¹A. Flückiger, 'Effectiveness: A New Constitutional Principle' 2009 *Legislação* 189.

²²Dutch Supreme Court 27 January 1961, ECLI:NL:PHR:1961:AG2059 (Prof. Van den Bergh).

²³Dutch Supreme Court 19 November 1999, ECLI:NL:PHR:1999:AA1056 (Tegelen/Limburg).

²⁴Dutch Supreme Court 14 April 1989, ECLI:NL:PHR:1989:AD5725 (Harmonisatiewet).

²⁵See for a more elaborate explanation of this idea of the primacy of the legislature: R. van Gestel, 'The "Deparliamentarisation" of Legislation' [2013] 9, 2 *Utrecht Law Review*, 106–122 <<https://www.utrechtlawreview.org/articles/abstract/10.18352/ulr.230/>>

²⁶Article 8:2 of the General Administrative Law Act.

²⁷A. Bok, *Rechterlijke toetsing van regelgeving* (Kluwer 1991) 4–5.

²⁸See recently Dutch Supreme Court 22 May 2015, ECLI:NL:HR:2015:1296 (Privacy First). This residual protection is only possible in case of a lack of sufficient legal protection in the proceedings before the administrative courts.

²⁹Dutch Supreme Court 16 May 1986, ECLI:NL:PHR:1986:AC9354.

³⁰S. Stoter, *Belangenafweging door de wetgever. Een juridisch onderzoek naar criteria voor de belangenafweging van de formele wetgever in relatie tot de belangenafweging op bestuursniveau* (Boom Juridische uitgevers 2000) 69–70.

is compatible with fundamental rights.³¹ If this is the case, a court must decide if the application of the rules in concrete cases may create unreasonable consequences. In both situations, the European Court of Human Rights (ECtHR) will apply a threefold test,³² as soon as it has established that there might be a limitation of human rights ‘prescribed by law’.

According to the ECtHR, Dutch courts first need to investigate whether a statute that restricts fundamental rights has a legitimate aim. Sometimes the treaty itself is clear about what sort of aims might justify a limitation of rights, as is the case in the articles 8–11 ECHR. In other cases, the court needs to decide for itself what sort of aims are legitimate. In practice, this might be quite difficult. The legislative history may be unclear and, when a statute is old, one may have doubts whether the legislature would still interpret the aims in the same vein. Furthermore, the limitation clauses of articles 8–11 of the ECHR are so broad that most legislative aims can be brought within these categories as long as the measures are ‘necessary in a democratic society’.³³ This means there should be a pressing social need that is proportionate to aims pursued by the legislature.³⁴

The second step in the review process for courts is to investigate whether legislative measures are ‘necessary’, ‘relevant’ and ‘sufficient’ to reach the aims set by the legislature. These criteria are interrelated because when answering if a certain measure is necessary, it is essential to know if there are regulatory alternatives to achieving the same goals.³⁵ It is understandable that the ECtHR leaves a wide margin of appreciation for governments because they are normally better equipped to decide what sort of measures are most effective to achieve certain aims. This is also where *ex ante* evaluation comes into play since the effectiveness of legislative measures is usually determined via different methods of *ex ante* evaluation, such as stakeholder consultations, impact assessments and cost-benefit analysis.

The judiciary is not capable of conducting *ex ante* evaluations but has the advantage of deciding with hindsight. The longer the period between

³¹See: ECHR April 22 1993, 15070/89, § 20–24 (Modinos/Cyprus); ECHR October 22 1981, 7525/76, § 40–41 (Dudgeon/United Kingdom) and ECHR October 26 1988, 10581/83, § 28–34 (Norris/Ireland).

³²J. Vande Lanotte and Y. Haeck, *Handboek EVRM. Deel 1: Algemene beginselen* (Intersentia 2005) 123.

³³Legitimate interests include national security; territorial integrity and public safety; the economic well-being of the country; the prevention of disorder or crime; the protection of health or morals; the protection of the rights, freedoms, and reputation of others; the prevention of disclosure of information received in confidence; and the impartiality of the judiciary. See R. Pati, ‘Rights and their Limits: The Constitution for Europe in International and Comparative Legal Perspective’ *Berkeley Journal of International Law* 252.

³⁴See ECtHR March 23 1983, 5947/72, 6205/73, 7052/75, 7061/75, 7107/75, 7113/75, 7136/75, § 97 (Silver *e.a./Verenigd Koninkrijk*) and ECtHR 7 December 1976, 5493/72. (*Handyside v. the United Kingdom*).

³⁵In that case the legislative measure is considered to be disproportionate. A. Nieuwenhuis, ‘Van proportionaliteit en appreciatiemarge: de noodzakelijkheidstoets in de jurisprudentie van het EHRM’, in: A.J. Nieuwenhuis, B.J. Schueler and C.M. Zoethout (eds.), *Proportionaliteit in het publiekrecht* (Kluwer 2005), 37. See for an example: ECtHR November 24 1993, 13914/88, 15041/89, 15717/89, 15779/89 en 17207/90, § 39–44 (Lentia *a.o./Austria*).

enactment and judicial intervention, the more likely it will therefore become that there are relevant independent sources that can provide information about the effectiveness of laws and regulations, such as ex post evaluations, scholarly publications, or amicus curiae briefs. Nonetheless, what will remain difficult for courts is to provide an objective opinion about the consideration of alternatives, because this would imply an inquiry into the availability of regulatory alternatives and an estimation of their effectiveness. This does not imply, though, that courts are unable to assess to what extent the legislature has conducted a proper ex ante evaluation, especially in case there are official guidelines, manuals or procedures for this.³⁶

A final step in the judicial proportionality test concerns whether there is a reasonable balance between the legitimate aims pursued by the legislature and the rights affected by the applicable legislative intervention. There is no objective method or yardstick to guide this balancing act. Moreover, where courts are used to balancing interests in concrete cases, the legislature needs to do this on a higher level of abstraction taking into account all possible future circumstances. Nevertheless, Gerards has argued that courts could more often force legislators to provide more and better information about the specific aims of legislative drafts and about the facts and (empirical) evidence on which legislative decisions rest.³⁷ In case the legislature cannot or will not supply this information, courts could consider issuing a 'declaration of inapplicability'. This would send a clear message to the legislature and facilitate a more intensive judicial review of legislation without overruling democratic legislative decisions.³⁸

4.3. Legislative rationality testing in practice by Dutch highest administrative courts

Most of the cases in which (primary) legislation is reviewed by Dutch highest administrative courts concern infringements against European human rights law or EU law. However, there have been hardly any attempts so far to challenge the evidence on which laws and regulations rest. There are a few exceptions to this rule, though. A still interesting older example is the *Fluoriderings*

³⁶For the Dutch situation this is certainly the case. Not only are there Guidelines for legislative drafting, which contain detailed provision as the steps that should be taken during the preparation of legislative drafts, but there is also the Integrated Assessment Framework (IAK) that guides draftsmen via an electronic programme through the different steps of the ex ante evaluation process.

³⁷J. Gerards, 'Wisselwerking tussen wetgever en rechter – naar een betere dialoog' in R. de Lange (ed.), *Wetgever en grondrechten, Publicaties van de Staatsrechtkring* (Wolf Legal Publishers 2008) 174–175, 179–180.

³⁸Although Gerards, inspired by the work of John Hart Ely, appears to accept that under certain circumstances, especially when the regular democratic decision-making process is frustrated, there might be a justification for judicial activism and interventions in the legislative process by courts. In the same sense: T. Koopmans, 'Rechterlijk activisme in Europees rechtelijk perspectief' in P. van Dijk (ed.), *De relatie tussen wetgever en rechter in een tijd van rechterlijk activisme* (KNAW 1989) 37.

case that was decided by the Supreme Court in 1970. It concerned a decision of the Amsterdam public water supply company to add fluoride to the drinking water to fight tooth decay. Citizens took the company to court because they did not believe the positive effects that fluoride was supposed to have. The Supreme Court ruled that:

[T]he addition of substances to our drinking water in order to serve a goal that lies completely outside the actual purpose of the public water supply [...] is such a fundamental decision, that without an explicit legal basis, the Amsterdam water company may not assume to have the freedom to add fluoride to the drinking water as part of the public task assigned to it by article 4, section 1 of the Water Supply Act.³⁹

The Supreme Court was of the opinion that adding substances to the drinking water for medical purposes without an explicit legal basis constitutes a form of ‘*détournement de pouvoir*’. Because the court decided the water-supply company had no competence to add fluoride to the water it did not get to a proportionality test *stricto sensu*. That is a pity because whether the fluoridation of drinking water actually had a preventative effect on tooth decay without having other adverse health effects was, and still is, contested in the medical world.⁴⁰ It would have been interesting to learn how the Supreme Court had operated in case there had been a legal basis for the water-supply company to add substances to the drinking water for healthcare purposes.

A case in which legislation was challenged through a proportionality review is the *Alcohol lock case*.⁴¹ In this case the administrative authority responsible for driver safety (*Centraal Bureau Rijvaardigheid*) required someone arrested for drunken driving to participate in a so-called alcohol lock programme in which the offender gets a special licence for driving a car that contains an alcohol lock, which prevents the car from starting before the driver passes a breathalyser test. The offender needs to bear the costs for the installation of an alcohol lock in his car. Refusing to participate in the programme results in an invalidation of one’s licence for five years. The offender in this case appealed against the decision to the Administrative Jurisdiction Division of the Council of State (AJD), claiming that Article 17 of the regulation introducing the alcohol lock measure (*Regeling maatregelen rijvaardigheid en geschiktheid 2011*) is disproportionate in its consequences. The AJD invalidated the regulation because of an infringement of Article 3:4 of the General Administrative Law Act. This provision holds that the

³⁹Dutch Supreme Court 22 June 1973, ECLI:NL:PHR:1973:AD2208 (Fluoridering II).

⁴⁰See: [http://www.thelancet.com/journals/laneur/article/PIIS1474-4422\(14\)70119-X/fulltext?hc_location=ufi](http://www.thelancet.com/journals/laneur/article/PIIS1474-4422(14)70119-X/fulltext?hc_location=ufi).

⁴¹The Council of State: 4 March 2015, ECLI:NL:RVS:2015:622.

consequences of a regulation may not be disproportionate to the legitimate aim pursued by the legislature.

Interestingly, the AJD collected evidence for its decision from past and pending cases. Based on the experience in these cases it noticed that: (a) the costs of the alcohol lock measure for citizens were, in practice, much higher than anticipated by the legislature. Offenders, who could not afford the installation of alcohol locks in their cars, were automatically confronted with an invalidation of their driver's licence for five years. Among those offenders are people who need their licence to make a living. Even for those who can afford to pay for the alcohol lock in their car, the consequences may be disproportionate. Just think of the case in which the offender needs to drive cars other than his or her own (e.g. the taxi driver). In such a case, the offender runs the risk of losing their job. Although the AJD found the consequences of the alcohol lock regulation in the individual case disproportionate, it refused to decide over the necessity and suitability of the alcohol lock programme to achieve the legislature's aims. This is a pity because it is exactly on these points the Advisory Division of the Council of State (AD) had criticised the alcohol lock programme. The AD, for example, noticed that the regulation was not linked with an intensive treatment programme for offenders to overcome their addiction, which left the underlying (addiction) problems intact. Moreover, the AD cast doubts on the susceptibility of the programme to fraud. Hence, there were previous doubts as to how effective the programme was going to be and whether there were no less intrusive alternative measures available to achieve the same goals.⁴²

Although the impression among Dutch politicians increasingly seems to be that courts are using fundamental rights and legal principles to steal terrain from the legislature, in reality Dutch courts leave the legislature a broad margin of appreciation.⁴³ Seldom do they interfere with policy decisions made by the legislature. A prominent exception is the ruling of the Supreme Court with regard to the anti-smoking legislation in Dutch pubs and restaurants that, until recently, allowed smoking in bars where the owner or manager was the only employee.⁴⁴ In 2014, the Supreme Court ruled that this exception ran against article 8(2) of the Framework convention on Tobacco Control.⁴⁵ After having determined that this provision is directly applicable in the national legal order, the Supreme Court decided that the convention obliges parties to the treaty to introduce effective protection against exposure to tobacco smoke in public buildings in order to prevent

⁴² Advisory opinion W09.08.0371/IV. See: https://www.raadvanstate.nl/adviezen/zoeken-in-adviezen/tekst-advies.html?id=8501&summary_only=&q=alcoholslot.

⁴³ J. Gerards and J. Fleuren (eds.), *Implementation of the European Convention on Human Rights and of the judgments of the ECtHR in National Case Law* (Intersentia 2014).

⁴⁴ Dutch Supreme Court 10 October 2014, ECLI:NL:HR:2014:2928.

⁴⁵ See: <http://apps.who.int/iris/bitstream/10665/42811/1/9241591013.pdf>.

serious health risks. In addition, the court ruled that the mere existence of a certain discretion, left by the treaty-giver to national legislatures, does not prohibit that Article 8(2) is directly applicable. This provision would not leave any room for an exception to allow for smoking in smaller pubs with single owners.

4.5. Legislative rationality testing by the advisory division of the Council of State

There are few cases where the highest administrative courts appear to be willing to look beyond the text and the explanatory memorandum of a piece of legislation in order to challenge the evidence and (empirical) assumptions on which the rules are built. This is remarkable because the ECtHR increasingly seems to apply a procedural test to scrutinise the proportionality of legislation.⁴⁶ It is also strange because during the preparatory phase of the law-making process, the AD of the Council of State points on a regular basis to a lack of valid evidence to support the assumptions on which a certain legislative draft is based in order to warn the legislature of an infringement of the proportionality principle.

To mention just a few examples: when the legislature tried to introduce a ban of Muslim women wearing burqas or niqabs, the AD concluded that a complete ban would not be necessary in a democratic society to protect the public. The AD saw no evidence that wearing such clothing resulted in a threat to public safety, while a ban could not prevent dangerous criminal activities.⁴⁷ In the case of a law that was meant to regulate the court custody of perpetrators of domestic violence for ten days, with the possibility of an extension, the AD advised shortening the cooling down period and increasing the procedural warranties of the person to be placed in custody in case of extension. The AD not only drew attention to the limited added value of custody compared with already available measures to deal with crisis situations, but also referred to existing research with regard to the effects of custody in Austria and Germany.⁴⁸ A final example concerns a law that provided the government with the right to send back ‘troubled youngsters’ from the Dutch Antilles and Aruba who had spent less than three years in the Netherlands.⁴⁹ One of the reasons the AD saw this measure as a disproportionate infringement of their EU right to citizenship,

⁴⁶P. Popelier and C. van den Heyning, ‘Procedural Rationality: Giving Teeth to the Proportionality Analysis’ (2013) *European Constitutional Law Review* 230, 252.

⁴⁷Parliamentary Papers II 2007–2008, 31 108, nr. 4 and 2011/2012, 33 165, nr. 4. The AD refers to an expert report. See: Overwegingen bij een boerkaverbod/Zienswijze van de deskundigen inzake een verbod op gezichtsbedekkende kleding, 3 November 2006, Bijlage bij Kamerstukken II 2006/07, 29 754, nr. 91, blz. 60.

⁴⁸Parliamentary Papers 2005–2006, 30 657, nr. 4, p. 7.

⁴⁹Parliamentary Papers 2006–2007, 30 962, nr. 4.

was that statistics showed that the majority of these people had already been in the Netherlands for more than three years, which made it very unlikely that the measure could be effective.

In these and other cases, the AD apparently wants to show to the legislature that if certain regulatory measures are not capable of achieving the aims mentioned in the act, or if lighter alternatives could reach the same result, the legislative draft runs against higher law and does not deserve to be passed. The AD apparently tries to anticipate how national courts and the ECtHR would react in case they have to decide over the legality of the draft after its enactment. This makes it even more surprising that Dutch highest administrative courts remain reluctant to look at *ex ante* evaluations or empirical evidence when they review the proportionality of laws and regulations.

5. Review of legislative rationality by the CJEU

5.1. Proportionality in the EU's legislative context

Article 52 of the Charter of fundamental rights of the EU reads:

Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.

With regard to how legislators and regulators should use their competences, Article 5(1) TEU contains a basic rule: 'The limits of Union competences are governed by the principle of conferral. The use of Union competences is governed by the principles of subsidiarity and proportionality.' The article provides a three-stage test. The first stage is to find out if EU institutions are competent to regulate in order to attain objectives set out in the treaties or in secondary legislation. This is important because the EU legislature has no 'Kompetenz-kompetenz', indicating there is nothing to regulate as long as there is no conferral of regulatory competences allowing EU institutions to act.⁵⁰ In that case, there is also a violation of the subsidiarity principle. After all, subsidiarity entails that in areas, which do not fall within its exclusive competence of the EU, the Union shall act only in case the proposed action cannot be sufficiently achieved by the Member States.⁵¹

In case there is a legal basis, the subsidiarity principle requires in stage two an explanation of why EU institutions are better equipped than national

⁵⁰In practice this is quite rare because of the wide range of competences since the Lisbon Treaty and the availability of 'flexibility clauses', such as the one laid down in article 352 TFEU, which may enable EU institutions to act even if a specific competence is lacking.

⁵¹Article 5(3) TEU.

authorities to regulate the problem. The only problem is that the ‘subsidiarity test’ laid down in the subsidiarity protocol annexed to the Treaty of Amsterdam seldom signals that the EU should refrain from action.⁵² The yellow/orange card procedure through which Member States can file complaints against EU legislative action has not proven to be an effective remedy against competence creep.⁵³ Finally, the CJEU is reluctant to strike down EU legislation because of a breach of the subsidiarity principle because this is considered to be a political matter.⁵⁴ However, some authors have argued that by using impact assessments and arguments from the Early warning system, the CJEU could strengthen its review of the subsidiarity principle without politicising its jurisprudence.⁵⁵

Stage three concerns proportionality *stricto sensu*. Here, article 5(4) TEU determines: ‘Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.’ This necessity test implies that EU laws and regulations should not go further than necessary to achieve the required policy goals. It also implies there are no less intrusive alternatives to accomplish these goals. This clarification follows from the case law of the CJEU,⁵⁶ and so does the requirement of suitability demanding that laws and regulations should be fit for purpose. It requires a logical connection between means and ends in legislative policy making. Proportionality means that regulatory instruments should be kept as simple and ‘light’ as possible without endangering the effectiveness of the policy.⁵⁷

In practice, the Commission is responsible for an assessment of the proportionality of legislative drafts for which it usually consults stakeholders. Consultations need to take into account the regional and local dimension of legislative acts where appropriate. Only in case of exceptional urgency may consultations be left aside but not without giving reasons.⁵⁸ The CJEU

⁵²See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2004:310:0207:0209:EN:PDF>.

⁵³See F. Fabbrini and K. Granat, ‘Yellow Card, but no Foul’: the Role of the National Parliaments under the Subsidiarity Protocol and the Commission Proposal for an EU Regulation on the Right to Strike’ (2003) *Common Market Law Review* 115–143.

⁵⁴G. de Búrca, ‘The Principle of Subsidiarity and the Court of Justice as an Institutional Actor’ (1998) *Journal of Common Market Studies* 217.

⁵⁵W. Vandenbruwaene, ‘Multi-Tiered Political Questions: The ECJ’s Mandate in Enforcing Subsidiarity’ (2012) *Legisprudence* 321–346.

⁵⁶See, for example, case C-137/85 *Maizena v BALM* [1987] para 15 case C-339/92, *ADM v Ölmühlen* [1993] para 15.

⁵⁷See in the meanwhile the withdrawn protocol attached to the Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts – with a protocol on the application of the principles of subsidiarity and proportionality, Official Journal C 340, 10/11/1997 P. 0105, under article 6) and article 296 TFEU stating that: ‘Where the Treaties do not specify the type of act to be adopted, the institutions shall select it on a case-by-case basis, in compliance with the applicable procedures and with the principle of proportionality.’

⁵⁸Article 2 of Protocol 2 to the Lisbon Treaty on the principles of subsidiarity and proportionality. See also Ombudsman decision in case 904/2014/OV on the European Commission’s public consultation prior to its legislative proposal for a Regulation concerning the European single market for electronic communications: <<http://www.ombudsman.europa.eu/nl/cases/decision.faces/en/60965/html.bookmark>>.

reviews the way in which the proportionality principle is taken into account by the legislature, but the way in which it tests the proportionality of legislative acts differs. In case of EU legal acts, a lenient ‘manifestly disproportionate’ test is applied. With regard to national laws and regulations, the CJEU usually undertakes a more rigorous and searching examination of the justification for national regulatory intervention with a special focus on the availability of less intrusive means to reach the policy goals.⁵⁹

5.2. Legislative rationality testing in practice by the CJEU

As the European Union is taking on more regulatory functions, there is increasing pressure on EU courts to act as regulatory watchdogs. Advocate General Sharpston has even argued that EU laws lacking an impact assessment should be held unlawful. Such laws would be arbitrary since they have not been put to the test, which runs against the fact that legislative choices need to be justified according to the proportionality principle.⁶⁰ The CJEU, however, has not followed the Advocate General’s opinion.

The number of cases in which the CJEU tests the rationality of legislation is still very limited. One reason might be that litigants who want to challenge EU legal acts face at least three major limitations. First, restrictive rules on jurisdictions and standing can make it difficult for them to ask the GC or CJEU to assess whether EU legal acts comply with procedural requirements, such as the need to conduct impact assessments or stakeholder consultations. One of the obstacles is still that private parties only have standing against ‘an act addressed to that person or which is of direct and individual concern to them, and against a regulatory act which is of direct concern to them and does not entail implementing measures.’ In the *Inuit* case, the CJEU decided that regulatory acts do not include legislative acts. The only way to challenge a legislative act is to claim that the act is of direct and individual concern to the applicant.⁶¹ This may prove to be difficult because of the nature of legislative acts is their general application. Secondly, regulatory quality requirements are often laid down in non-enforceable policy guidelines, recommendations and other forms of soft law of which the legal status is unclear. Thirdly, so far EU courts have been quite hesitant to conduct an intensive proportionality review of EU legislative acts, although the CJEU seems to feel more confident to put national legislation to the test.⁶²

⁵⁹W. Sauter, ‘Proportionality in EU Law: A Balancing Act?’ (2013) TILEC Discussion Paper No. 2013-003, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2208467>.

⁶⁰Case C-310/04 *Spain v Council* [2006] of AG Sharpston paras para 80–81.

⁶¹Case 538/11.

⁶²S. Rose-Ackerman, S. Egidy and J. Fowkes, *Due Process of Lawmaking: The United States, South Africa, Germany, and the European Union* (Cambridge University Press 2015) 237–238.

An example of the latter is a Belgian case in which the CJEU clarified the justifications, which Member States may legitimately invoke, in support of certain measures restricting the free movement of university students.⁶³ In this case, the French Community had adopted a ‘*numerus clausus*’ requirement to restrict the number of non-resident French students in certain university courses, such as the study of medicine, in order to prevent the situation in which foreign students would return home after their studies, leaving the Belgian government with a shortage of professionals. This case was brought before the Belgian Constitutional Court, which put questions to the Court of Justice on the interpretation of the principle of non-discrimination on the ground of nationality (Article 18 of the TFEU) and freedom of movement (Article 21 of the TFEU), in conjunction with the provisions on the mobility of students and trainees (Articles 165 and 166 of the TFEU). Summarising the decision by the CJEU, the court found that:

The legislation at issue creates a difference in treatment between resident and non-resident students, which constitutes indirect discrimination on the ground of nationality as prohibited by the Treaty, unless there is an objective justification. First of all the CJEU rejects as unfounded the justification of the excessive burden on public finances caused by the influx of foreign students. Regarding the risk that the quality of education would be jeopardised and the quality of the public health system in the French Community would be put at risk, the Court accepts that in principle national legislation which is indirectly discriminatory may be justified by requirements of this nature, but leaves it up to the national court, which has sole jurisdiction to assess the facts and interpret the national legislation, to determine whether and to what extent such legislation satisfies the requirements in question. However, the CJEU provides guidance to the Belgian Constitutional Court to assist it in its assessment by determining that this court will have to ascertain – on the basis of an objective, detailed analysis and solid, consistent data provided by the Belgian authorities – that there are genuine risks to public health. It must then assess, in the light of the evidence provided by the competent authorities, whether the legislation at issue can be regarded as appropriate for attaining the objective of protecting public health and in particular whether a limitation of the number of non-resident students can really bring about an increase in the number of graduates ready to ensure the future availability of public health services within the French Community. Finally, the CJEU decided that the Constitutional Court will have to ascertain whether the objective in the public interest relied upon could not be attained by less restrictive measures.

Although the CJEU does not (yet) seem to view impact assessments as an essential requirement for the legality of legislative decisions in this case, it does require a strengthening of the evidence-base for a *numerus clausus*. Moreover, impact assessments can be important in the assessment of the proportionality of legislative acts. Probably the most prominent example of how

⁶³Case c-73/08 *Bressol Chaverot v Gouvernement de la Communauté française* [2010].

this works stems from the *Vodafone* case, in which the CJEU had to decide over the legality of Regulation 717/2007, which was adopted to fix the maximum fees that mobile phone operators may charge for voice calls made and received by users outside their own network by introducing a 'Euro-tariff'.⁶⁴ One of the central questions in the case is whether by imposing a Euro-tariff, the EU-legislature had violated the principles of proportionality and subsidiarity.

The CJEU answers this question by recalling that the legislature enjoys broad discretion.⁶⁵ Yet the CJEU points out that the exercise of that discretion should be based on objective criteria.⁶⁶ The Court found that before the Commission proposed the regulation, it carried out an exhaustive impact assessment of alternatives and evaluated the economic impact of various types of regulations. The average retail charge for a roaming call in the EU at the time the regulation was adopted was high (as the impact assessment pointed out: more than five times higher than the actual cost of providing the wholesale service) and the relationship between costs and prices was not such as should have prevailed in fully competitive markets. The tariff provided for in the regulation is significantly below that average charge and is set in relation to the ceilings for the corresponding wholesale charges, so that the retail charges reflect more accurately the costs incurred by providers. In those circumstances, according to the CJEU, an intervention limited in time (by a sunset provision) in a market that is subject to competition, which makes it possible, in the immediate future, to protect consumers against excessive prices, such as that at issue, is proportionate to the aim pursued, even if it might have negative economic consequences for certain operators. Because Member States lack the regulatory competence in the wholesale market and could not impose a price ceiling on a mobile operator located in another Member State, compliance with the principle of subsidiarity was self-evident.

As Lenaerts has observed, *Vodafone* is interesting because it shows that the CJEU applies the proportionality principle in a procedural fashion. Instead of conducting a substantive review, the EU legislature was obliged to show to the court that it had taken into account all relevant interests and examined different regulatory options and their social, economic and environmental impact before deciding to impose a price ceiling in the retail roaming market.⁶⁷ Brenncke noted that the further the CJEU goes in this procedural review, the more it would alleviate the disadvantages of a marginal judicial review of substantive issues.⁶⁸ In *Vodafone*, the CJEU decided not to limit

⁶⁴Case c-58/08 *Vodafone and Others v. Secretary of State for Business, Enterprise and Regulatory Reform* [2010].

⁶⁵Only where an EU measure is manifestly inappropriate to the objectives it pursues will the CJEU rule that it runs against the proportionality principle. See: Case c-189/01 *Jippes and Others* [2001] ECR I-5689, paras 82–83; *British American Tobacco (Investments) and Imperial Tobacco*, para 123; *Alliance for Natural Health and Others*, paragraph 52; and Case C-558/07 *S.P.C.M. and Others* [2009] ECR I-0000, para 42.

⁶⁶Para 52.

⁶⁷Lenaerts (n 9) 7.

⁶⁸M. Brenncke, Case note (2010) 47 *CMLR* 1793 at 1809.

its scrutiny of legislation to a formal reading of the preamble of a regulation. Whenever necessary, the CJEU will also take explanatory memoranda and impact assessments into account to verify the evidence-base on which EU laws rest.

Craig even seems to go further by claiming that if justificatory reasons for the use of legislative power in an impact assessment are missing, with the accompanying risk of competence creep, the CJEU should invalidate the legislative instrument and send a clear message to political institutions that this runs against the treaties. With hindsight, this is exactly what had happened in the case *Spain vs Council* with regard to a Community support system for the production of cotton as adopted by Regulation 1782/2003.⁶⁹ This regulation was challenged because of the proportionality principle by Spain, because by fixing the amount of aid to 35% of the existing aid under the previous scheme, the regulation would be unable to guarantee the profitability of the cotton production. The CJEU sided with Spain and argued that the margin of discretion left to the EU legislature does not exempt it from taking into consideration the relevant factors and circumstances of the situation the act was supposed to regulate. The CJEU subsequently ruled that:

the institutions must at the very least be able to produce and set out clearly 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.⁷⁰

Here, the CJEU was clearly hinting at the absence of a proper impact assessment. Since neither the Council nor the Commission had provided facts to support the fixation of the amount of aid to 35%, the CJEU had no other choice than to annul the contested Regulation, according to Judge Lenaerts.⁷¹ This does not imply, as Advocate General Sharpston seemed to argue, that ignoring the results from an impact assessment would automatically invalidate the underlying act, for the simple reason that in some cases legislative drafts may undergo serious amendments after the impact assessment has been conducted. That is probably why the CJEU took a more limited approach in the *Afton Chemical* case where it required that amendments to a legislative draft should be based on relevant scientific data, but without requiring an impact assessment.⁷² However, if the CJEU cannot always rely on the content of an impact assessment, how does it know that empirical data or other scientific evidence is relevant, valid, and trustworthy?

A good example is the *Test-Achats* case in which the CJEU had to assess whether article 5(2) of Directive 2004/113 exceeded the limits that compliance

⁶⁹Case C-310/04 *Spain v Council* [2006] ECR I-7285.

⁷⁰*Ibid.*, para 123.

⁷¹Lenaerts (n 9) 8.

⁷²Case C-343/09 *Afton Chemical v Secretary of State for Transport* [2010] ECR I-07027.

with the principle of proportionality imposes. Article 5(2) permits proportionate differences in individuals' insurance premiums and benefits where the use of sex is a determining factor in the assessment of risks based on relevant and accurate actuarial and statistical data. As stated in recital 18 to Directive 2004/113, the use of actuarial factors related to sex was widespread in the provision of insurance services at the time when the directive was adopted. This was the actual rational underpinning of article 5(2) of Directive 2004/113. However, the CJEU ruled article 5(2) to be invalid upon the expiry of an appropriate transitional period because article 5(1) of the same directive provided that differences in premiums and benefits arising from the use of sex as a factor in the calculation thereof must be abolished after a transition period.

The CJEU apparently saw an inconsistency because article 5(2) initially allowed a permanent exemption from the rule of unisex premiums. According to Lenaerts, this judgment teaches us that the principle of proportionality is not applied in an abstract fashion, 'but as part of the legal and factual context in which the contested measure operates'.⁷³ Can this be seen in isolation from the rational underpinning of the provision and consequences this ruling will have for the insurance practice in the Member States? At first sight, the ruling may be seen as a subtle decision that simply takes away the basis for unjustified discrimination and an inconsistency within the legislative act. Different premiums on the basis of risk are still allowed but insurers 'just' have to find more objective grounds for calculating their premiums, one is inclined to say. The story is not that simple though.

In terms of insurance premiums, *Test Achats* has led to largely insignificant benefits for the former disadvantaged and to a dramatic increase in premiums for those who were formerly considered to be the 'better risks'.⁷⁴ So, in the end, all consumers (men and women) are probably worse off than before the court ruling because the CJEU seems to have overlooked that there is an inherent injustice in every statistical classification, be it based on sex, age, wealth or even the type of car one drives. After all, the fact that women *in general* live longer or that cars with more horsepower are *generally* more often involved in accidents does not say anything about the life expectancy of a *particular* woman or does not mean that an *individual* car-owner cannot drive a very fast car for years without getting into an accident. The use of actuarial tables as such is always a matter of 'injustice by generalisation', because an individual woman might live a far healthier life than her husband and hence have a shorter life expectancy. The husband in his turn, who is driving a sports car, may very well be able to show that he has a far

⁷³Lenaerts (n 9)15.

⁷⁴E. Schanze, 'Injustice by Generalization: Notes on the Test-Achats Decision of the European Court of Justice' (2013) *German Law Journal* 423.

better track record of safe driving than his neighbour who drives a super-safe car but has lost his driver's licence several times for drunken-driving. According to the actuarial tables, however, these individual particularities are irrelevant because it is the *average* risk that matters.

Discrimination in this case probably cannot be ruled out by a simple unisex formula. If we, for example, allow different premiums for different types of cars, and women happen to prefer certain types of cars to men due to socio-psychological factors, this could represent a higher risks-category to insurers that could still be calculated into the premium. Therefore, there would remain indirect 'discriminatory' effects. If policy makers or legislators want to rule out these indirect effects, highly complex, expensive, and privacy-intrusive, psychometric and medical tests would need to be introduced to replace the criterion of gender-differences and the effect they have, in general, on certain types of behaviour. One may wonder to what extent the EU legislature realised all this when prohibiting, in article 5(1) of Directive 2004/113, from 21 December 2007 onwards, the use of sex as a relevant factor in the calculation of premiums and other benefits for the purposes of insurance and related financial services.

Another case where the principle of equal treatment and the need for solid scientific evidence played an important role is the case *Léger v Ministre des Affaires sociales, de la Santé et des Droits des femmes and Etablissement français du sang*.⁷⁵ This case dealt with the permanent deferral from blood donation for men who have had sexual relations with other men because those persons might be at a high risk of acquiring severe infectious diseases, such as HIV. On 29 April 2009, a doctor at the French Blood Agency in Metz refused the blood donation offered by Mr Léger on the ground that he had had sexual relations with another man, and that French law permanently excludes blood donations from men who had had such relations. As Mr Léger challenged that decision, the Tribunal administratif de Strasbourg asked the CJEU whether such a permanent deferral is compatible with Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC regarding certain technical requirements for blood and blood components.⁷⁶ According to this directive, persons whose sexual behaviour puts them at a high risk of contracting severe infectious diseases that can be transmitted by blood are subject to a permanent deferral from blood donation.

The CJEU first issued that the Tribunal administrative de Strasbourg needs to determine whether, in France, there really is a high risk of acquiring severe infectious diseases by blood donations due to sexual intercourse between men. Secondly, the CJEU required the Tribunal to take account of the

⁷⁵Case c-528/13 *Léger v Ministre des Affaires sociales, de la Santé et des Droits des femmes and Etablissement français du sang* [2015].

⁷⁶OJ 2004 L 91, p. 25.

epidemiological situation in France, which, according to the French Government and the Commission, has a specific character because the data submitted to the Court, in the period 2003 to 2008, revealed that almost all HIV infections were due to sexual relations. Half of those newly infected were men who had sexual relations with other men. During the same period, this group was severely affected by HIV, with a much higher rate of infection than for the heterosexual population in France and ranked as the highest in Europe. Therefore, the Tribunal would have to ascertain whether, in the light of current medical, scientific and epidemiological knowledge, these data are reliable and still relevant.

According to the CJEU, even if the risk of acquiring diseases, such as HIV, among homosexual men might be significantly higher, the question would still be whether a permanent contraindication to blood donation is consistent with the principle of non-discrimination on the basis of sexual orientation as laid down in Article 21(1) of the Charter of Fundamental Rights. The CJEU recalled that any limitations on the exercise of the rights and freedoms from the Charter may be imposed only if they are necessary and genuinely meet objectives of general interest recognised by the EU or by the need to protect the rights and freedoms of others. The CJEU also ruled that although permanent deferral provided for in French law helps to minimise the risk of transmitting infectious diseases and, therefore, to the general objective of ensuring a high level of health protection, the principle of proportionality might still be violated. This could be the case if HIV can be detected by effective techniques able to ensure a high level of health protection for recipients. The national court will have to verify whether such techniques exist, it being understood that the tests must be carried out in accordance with the most recent scientific and technical procedures. In case such techniques do not yet exist, the Tribunal will have to ascertain whether there are less onerous methods of ensuring a high level of health protection other than permanent deferral from blood donation and, in particular, whether the questionnaire and the individual interview with a medical professional are able to identify high risk sexual behaviour more accurately.⁷⁷

Although the logic of the CJEU is understandable, national courts are now left with the problem of how to verify the risk of blood donations by homosexual men. How should they decide whether, for example, questionnaires and interviews with a medical professional are reliable less onerous methods than deferral from blood donations? Or, to put it differently, how would the national court need to decide when other scientific methods are 'sufficient' to minimise the risk of transmitting infectious diseases? What would be the yardstick for that? In case one opts for permanent deferral,

⁷⁷Case c-528/13 *Léger v Ministre des Affaires sociales, de la Santé et des Droits des femmes and Etablissement français du sang* [2015], para 66.

the risk of transmitting diseases is close to zero. It is highly likely that every other scientific method of screening blood or blood donors will always keep a residual risk. How could one objectively decide the amount of risk that is still acceptable then? Moreover, how should the national court conduct such a comparison between different (scientific) screening methods and are courts capable of doing so?

How complicated may be investigative proceedings by national courts also became clear in another recent CJEU case concerning the rights of homosexuals.⁷⁸ The three litigants from Gambia (A), Afghanistan (B) and Uganda (C), were disbelieved with respect to their sexual identity as gay men by Dutch immigration authorities. The Administrative Jurisdiction Division of the Dutch Council of State, considered that it needed guidance on whether having self-identified that they were gay men, the mere fact of further investigation could infringe on Articles 3 (right to integrity) and 7 (right to respect to private and family life) of the EU Charter of Fundamental Rights. Therefore, the court posed a preliminary reference to the CJEU asking:

What limits do Article 4 of Council Directive 2004/83/EC of 29 April 2004 on minimum standards for the qualification and status of third country nationals or stateless persons as refugees or as persons who otherwise need international protection and the content of the protection granted, and the Charter of Fundamental Rights of the European Union, in particular Articles 3 and 7 thereof, impose on the method of assessing the credibility of a declared sexual orientation, and are those limits different from the limits which apply to assessment of the credibility of the other grounds of persecution and, if so, in what respect?

In other words, how does one prove a gay asylum claim? The CJEU is clear in its decision about what is not allowed. Article 4 of Directive 2004/83, read in light of Article 7 of the Charter of Fundamental Rights of the European Union, must be interpreted as precluding the competent national authorities from carrying out detailed questioning as to the sexual practices of an applicant for asylum. Article 4 of Directive 2004/83, read in the light of Article 1 of the Charter of Fundamental Rights, precludes the acceptance by the responsible authorities of evidence, such as, the performance by the applicant of homosexual acts, his submission to 'tests' with a view to establishing his homosexuality or, yet, the production by him of films of such acts. Article 4(3) of Directive 2004/83 and Article 13(3)(a) of Directive 2005/85 must be interpreted as precluding the competent national authorities from finding that the statements of the applicant for asylum lack credibility merely because the applicant did not rely on his declared sexual orientation on the first occasion he was given to set out the grounds for persecution. In summary, the assessments cannot be based on stereotypes, on the questioning

⁷⁸Case c-148/13 *Staatssecretaris van Veiligheid en Justitie v UNHRCR* [2014] and C-150/13, *A, B and C v Staatssecretaris van Veiligheid en Justitie* [2013].

of sexual practices, on tests to identify sexual identity, or on the fact that the applicants have delayed openness about his homosexuality in the asylum process. Ultimately, the CJEU ruled that self-identification is the starting-point and that the ‘assessment must take account of the individual situation and personal circumstances of the applicant’ but what guidance does that provide for national courts and immigration authorities as to how one should deal with these types of claims?⁷⁹ What sort of ‘evidence’ could serve to filter out wrongful asylum claims in this respect? In addition, how should one establish the validity of this evidence?

6. Intermediate conclusion

In the relationship between courts and legislatures, proportionality analysis is about the justification of policy interventions and the effectiveness of regulatory measures to achieve policy goals, which may have an effect on citizens’ rights. Assessing the proportionality of legislative interventions presupposes a balancing between the aims of a legislative intervention and a rights provision or legitimate public interest that is limited by the intervention, which inevitably involves political choices. What we have seen above, though, is that this should not necessarily withhold courts from assessing the evidence-base of legislation, although the way the CJEU and national courts go about it, the tests they apply, and the intensity of judicial review, vary according to the applicable framework: EU law, national law or ECHR law.

Nonetheless, on a somewhat higher level of abstraction, the essentials of a proportionality test are not so different. As Stone Sweet and Mathews have argued, proportionality analysis in general consists of four components: (1) testing the *legitimacy* of a disputed regulatory measure by confirming the government is constitutionally authorized to act; (2) verifying that the means adopted by the government are *suitable* and rationally related to stated legislative objectives and, in principle, capable of meeting the aims pursued by the legislature; (3) critically reviewing the *necessity* of the regulatory intervention by ensuring that the measure does not curtail the rights of those affected any more than is necessary for the government to achieve its stated goals, which implies there are no less-intrusive alternatives available; (4) balancing between the *cost and benefits* (in the broad sense and not only in monetary terms) incurred by infringement of the right by the legislature, in order to determine which constitutional values shall prevail.⁸⁰

In particular, this last element makes it that proportionality assessment will always remain a matter of sailing between Scylla and Charybdis. If judges defer too much to legislators, they run the risk of selling out or balancing

⁷⁹*Ibid.*, para 57.

⁸⁰A. Stone Sweet and J. Mathews, ‘Proportionality Balancing and Global Constitutionalism’ (2008) *Columbia Journal of Transnational Law* 68–149.

away fundamental rights for the sake of effective law and policy making, whereas if courts are too restrictive and refuse to leave policy discretion to legislators, judges will probably be accused of overruling democratic decision making processes, which should be left to the legislative branch. To what extent the scrutiny of legislation by courts on the basis of a proportionality analysis will result in judicial activism ultimately depends on whether the judiciary succeeds in setting up a constructive dialogue with the legislature. As soon as we start seeing courts and legislatures more as partners in the process of law making, it will become clear that abstract ex ante evaluation of legislation by preferably independent advisory bodies or parliamentary committees, and more concrete ex post evaluation by the judiciary could supplement each other.⁸¹ Paradoxically, the more specific information policy makers and legislators provide about the aims of the drafts, the choice of regulatory instruments and the methods of ex ante evaluation, the more intensive a proportionality test by the judiciary may become. It is hard to predict if legislators will be prepared to shoot themselves in the foot by limiting their own discretionary powers once courts start to use voluntary ex ante evaluations against them.

Comparing the case law from the CJEU with the one from Dutch highest administrative courts, the message appears to be that the CJEU is more inclined to take ex ante evaluations, empirical data and scientific evidence on board than the Dutch courts. In the Netherlands, there is little enthusiasm to apply a rigid proportionality test to legislative acts. Dutch courts in general seem to leave much leeway for legislators and regulators to make policy decisions without questioning the evidence-base of these decisions. Although, strictly speaking, Dutch courts could apply a more rigid proportionality test even to acts of parliament as soon as EU law or ECHR law is involved, the legal culture is one of deference. This is probably not only caused by the idea that the judiciary should respect the primacy of parliament, but also because legislators are considered to be better equipped to scrutinise the validity of the facts, data and science on which laws are built.

The latter raises three questions. The first one is: why would the CJEU believe that it is more entitled to conduct a procedural review of national

⁸¹In Finland, for example, the introduction of ex post judicial review of legislation has strengthened the ex ante review of legislation with regard to constitutional aspects. See K. Turori, 'Combining Abstract ex ante and Concrete ex post Review: The Finnish Model' (Venice Commission 2010) see <[http://www.venice.coe.int/webforms/documents/default.aspx?pdffile=CDL-UD\(2010\)011-e](http://www.venice.coe.int/webforms/documents/default.aspx?pdffile=CDL-UD(2010)011-e)>. In the United Kingdom, Murray Hunt has described how, at the beginning of the twenty-first century, parliament has taken over a major part of the responsibility for the protection of the constitutionality of legislation from the civil service in terms of prelegislative scrutiny. He believes this is first and foremost due to a more active role of three parliamentary committees, the Joint Committee on Human Rights, the Delegated Powers and Regulatory Reform Committee and the Constitution Committee. The Parliamentary Counsel has shifted its attention more towards preparing lawyers from the ministries for the scrutiny that the three committees will employ. See M. Hunt, 'The Joint Committee on Human Rights' in A. Horne, G. Drewry and D. Oliver (eds.), *Parliament and the Law* (Hart Publishers 2013) 223–250.

legislation than domestic courts? Secondly, the CJEU case law shows that a procedural review of legislation can sometimes be very unsatisfying, especially when the evidence on which laws are based is controversial. In that case, a procedural review might lead to ‘scientific avoidance’ as was the case in both the blood donation and gay asylum examples. How should national legislators, for instance, develop a reliable ‘test’ to filter out dangerous blood transfusions from homosexual men or to detect fake gay asylum claims without running the risk of discrimination? It is relatively easy to suggest that alternative filtering mechanisms need to be considered by the national authorities, but far more difficult to determine which methods are proportionate and scientifically sound. Thirdly, it is interesting that the Dutch Council of State’s legislative advisory division, which has much more knowledge about ex ante evaluations of legislation than the administrative jurisdiction division, is more inclined to include empirical data and scientific evidence in the assessment of the proportionality of legislative drafts.⁸² This can only partly be explained by the fact that the advisory division is not bound by article 120 of the constitution and has given itself a duty to also assess the effectiveness and efficiency of legislative drafts.

What the CJEU and the Dutch courts have in common is that they are hesitant to look beyond a procedural review in order to challenge the facts, empirical data and scientific knowledge applied by legislators and regulators. One of the explanations for this might very well be that both EU and national courts feel insecure about the way in which the quality of this type of evidence should be assessed and the consequences this could have for the position of the judiciary. With regard to this, it might be helpful to look to the US for inspiration because the US Supreme Court has developed certain standards for judicial evaluation of empirical data and scientific evidence. These tests are better known as the Daubert doctrine.

7. Lessons to be learned from Daubert

An interesting question is what European courts might learn from the evidentiary standard announced in *Daubert v. Merrell Dow Pharmaceuticals*, which governs the admissibility of expert evidence in federal courts and state courts in the US.⁸³ In *Daubert*, the US Supreme Court made clear that courts need to ensure that expert testimony is both relevant and reliable, with the reliability test focusing on:

⁸²There is, however, also criticism regarding the way the AD uses empirical data and scientific research in its policy analytical review of legislation See R. van Gestel and J. Vranken, ‘Assessing the Accuracy of Ex Ante Evaluation through Feedback Research: A Case Study’ in J. Verschuuren (ed.), *The Impact of Legislation: A Critical Analysis of Ex Ante Evaluation* (Martinus Nijhoff 2009) 199–229.

⁸³509 US 579 (1993). Not every state court is always very strict in applying the US Supreme Court *Daubert* doctrine.

- (a) testability or falsifiability;
- (b) peer review and publication;
- (c) the known or potential rate of error; and
- (d) the degree of acceptance in the scientific community in a certain field.

In essence, Daubert aims to ensure that scientific evidence brought before courts by litigating parties meets the same standards of reliability that the relevant scientific field itself would require. After *Daubert v. Merrell Pharmaceuticals*, the case of *General Electric v. Joiner* added that the appellate court should review the trial court on its use of the Daubert factors.⁸⁴ This confirmed that courts are seen as ‘gate keepers’ responsible for filtering out the use of ‘junk science’ in the law-making process. Additionally, *Kumho Tire Co. v. Carmichael* added that the Daubert test applies to all fields of expert evidence and not only ‘science’ but also, for instance, to social and economic studies.⁸⁵ So far, however, the Daubert doctrine does not apply to legislation and agency regulation but it is contested whether the introduction of a ‘regulatory Daubert’ rule is needed (see hereafter).

Scholars have debated the overall efficacy of the Daubert test. Some look at it with great scepticism, mainly due to the vagueness of the criteria used to filter out substandard evidence.⁸⁶ This also appears to be the conclusion from a survey among judges, who in general seem to find the criteria useful, but hard to apply in a consistent manner.⁸⁷ This is why some scholars argue that the legislature should provide specific guidelines to test the quality of the expert evidence.⁸⁸ At the same time, many scholars feel that Daubert has at least made courts more sensitive and critical with regard to the screening of empirical data and scientific evidence more in general.⁸⁹ Moreover, Breyer has argued that the search for law reflecting a solid evidence base should not be mistaken for a search for scientific precision:

One could not hope to replicate the subtleties and uncertainties that characterize good scientific work. A judge is not a scientist and a courtroom is not a laboratory. [...] Rather, the law must seek decisions that fall within the outer

⁸⁴522 US 136 (1997).

⁸⁵526 US 137 (1999).

⁸⁶L. Heinzerling, ‘Doubting Daubert’ (2006) 14 *Journal of Law and Policy* 65 and E. Beecher-Monas, ‘Blinded by Science: How Judges Avoid the Science in Scientific Evidence’ (1998) 71 *Temple Law Review* 55.

⁸⁷S. Gatowski et al., ‘Asking the Gatekeepers: A National Survey of Judges on Judging Expert Evidence in a Post-Daubert World’ (2001) 25 *Law & Human Behaviour* 433.

⁸⁸C. Welch, ‘Flexible Standards, Deferential Review: Daubert’s Legacy of Confusion’ (2006) *Harvard Journal of Law and Public Policy* 1085. S. Ramsey and R. Kelly, ‘Assessing Social Science Studies: Eleven Tips for Judges and Lawyers’ (2006) 40 *Family Law Quarterly* 367.

⁸⁹E. Cheng and A. Yoon, ‘Does Frye or Daubert Matter? A Study of Scientific Admissibility Standards’ (2005) 91 *Vanderbilt Law Review* 471 and E. Hammon Meazell, ‘Scientific Avoidance: Toward More Principled Judicial Review of Legislative Science’ (2009) 84 *Indiana Law Journal* 239, 253.

boundaries that mark the scientifically sound decisions that, *roughly* speaking, *approximately* reflect the scientific 'state of the art'.⁹⁰

This being said, one has to be aware of the fact that the Daubert doctrine is no panacea. US Courts have so far consistently rejected applying the Daubert criteria to judicial review of agency decision making, although a few decisions, mostly from the Seventh Circuit, have invoked the test to inform their review of agency determinations, even while acknowledging that Daubert itself is not binding for regulatory agencies.⁹¹ In the meantime, the foundations of these separate institutional worlds have begun to collide due to the Information Quality Act (IQA) of 2001.⁹² The IQA imposes an evidentiary screening process on regulatory agencies that looks somewhat like the Daubert test and provides stakeholders in the regulatory process with the opportunity to file complaints for 'correction' of information disseminated by agencies they believe is unreliable. This correction process is aimed at excluding unreliable information from public dissemination or agency use and includes an appeal process inside the agency.

Those in favour of introducing a Daubert test in the realm of judicial review of laws and regulations claim that good science is good science, regardless of the context. As Raul and Dwyer put it:

The same 'good science' rationale should also apply to judicial review of the science underlying regulatory decision-making. Indeed, if private litigants are entitled to rules requiring sound science to protect parochial interests, certainly the public should be equally assured that good science is the foundation for national action.⁹³

Opponents of the extension of the Daubert test to judicial review of regulation have had the upper hand so far. First, they object because regulatory decision-making is much more forward looking compared with judicial law-making, anticipating possible risks that may or may not present themselves in the future.⁹⁴ Secondly, some scholars argue that judges are lacking the expertise to assess scientific evidence, while legislators and regulators would be more capable of doing so. Judges usually lack scientific or technical backgrounds themselves and, unlike regulatory agencies and legislators, courts simply cannot wait for new scientific information to become available before deciding the best course of action. They simply do not have the luxury of being able

⁹⁰S. Breyer, 'The Interdependence of Science and Law' (1998) 82 *Judicature* 24 (emphasis is in the original).

⁹¹D. Bernstein, 'What to do about Federal Agency Science: Some Doubts about Regulatory Daubert' (2015) *George Mason Law Review* 549.

⁹²W. Wagner, 'Importing Daubert to Administrative Agencies through the Information Quality Act' (2004) *Journal of Law and Policy* 589–617.

⁹³A. Raul and J. Dwyer, "'Regulatory Daubert': A Proposal to Enhance Judicial Review of Agency Science by Incorporating Daubert Principles into Administrative Law' (2003) *Law & Contemporary Problems* 7.

⁹⁴D. Bernstein, 'What to do about Federal Agency Science: Some Doubts about Regulatory Daubert' (2005) *George Mason Law Review* 553.

to take their time. Besides, courts sometimes have difficulties with science because of the nature of the adversarial system. Parties have every incentive to produce evidence favourable to their respective sides, regardless of the quality of the evidence and the science on which it is based.⁹⁵ Thirdly, some experts feel that judicial interference with the way regulatory agencies incorporate empirical data and scientific evidence in the rule-making process runs the risk of getting involved in policy-decisions that may affect judicial objectivity.⁹⁶

Some counter-arguments are also available. After all, not only legislators and regulators are dealing with problems that may present themselves in the future, in particular the highest courts often set precedents which introduce new rules that go far beyond the interests of individual litigants. In that case, it is important for courts to anticipate the consequences of their decisions while things may easily go wrong, as for instance the *Test Achats* case of the CJEU clearly shows. It is certainly true that most highest courts have not invested as much as legislatures and regulatory agencies in methods of ex ante evaluation, but this does not imply that courts should be given carte blanche when developing new legal rules. Courts are just as responsible as legislators to undertake a proper ‘*Folgenorientierung*’ and inform themselves with,⁹⁷ for example, *amicus curiae* briefs or independent court-appointed experts in case they consider introducing new law. In case one would feel that courts are not equipped to do so, we perhaps need to think how to better facilitate the judiciary on this point instead of avoiding the issue. As far as institutional disadvantages are concerned, the proposition that legislatures are better equipped to engage in careful fact-finding is usually taken for granted and leads to courts’ traditional deference to the legislature in case of problems surrounded by scientific uncertainty. Meazzel has argued that a more critical examination is needed of the comparative abilities of courts and legislatures to incorporate ‘good science’ into their decision-making. He doubts whether courts are always more poorly situated to resolve the type of scientific questions underlying regulatory decision-making than legislators and regulators.⁹⁸

On the surface, courts face some hurdles with respect to scientific evidence that legislatures can avoid. Although this argument is frequently used as a rationale for judicial restraint, there seems to be little empirical evidence

⁹⁵W. Kat, ‘Roper and the Scientific Amicus’ (2008–9) 49 *Jurimetrics* 253. Also E. Hammon Meazzel, ‘Scientific Avoidance: Toward More Principled Judicial Review of Legislative Science’ (2009) 84 *Indiana Law Journal* 239, 255.

⁹⁶T. McGarity, ‘On the Prospect of “Daubertizing” Judicial Review of Risk Assessment’ (2003) *Law & Contemporary Problems* 155, 156. Also D.E. Bernstein, ‘What to do about Federal Agency Science: Some Doubts about Regulatory Daubert’ (2015) *George Mason Law Review* 553.

⁹⁷C. Coles, *Folgenorientierung im richterlichen Entscheidungsprozeß* (Peter Land 1991).

⁹⁸H. Meazzel, ‘Scientific Avoidance: Toward More Principled Judicial Review of Legislative Science’ (2009) 84 *Indiana Law Journal* 239, 242.

that legislators and regulatory agencies are better fact finders than courts. Of course, the latter usually have more time, facilities and resources than courts. However, the fact that legislatures and regulatory agencies have better tools at their disposal does not lead to the conclusion that these tools are always used effectively. The legislative process suffers from some weaknesses that are different from those of the judicial procedure. Legislators and regulatory agencies may, for instance, have an incentive to present science in a way that fits best a particular political decision because the initiators of a certain law have an interest in the outcome. This is why providing counter-arguments and counter-evidence is often left to third parties. In the European context, the Commission may leave the reasons against a certain regulation or directive to the European Parliament and a regulatory agency could leave it to representatives of the Member States or to NGOs. Courts usually do not have this problem since they are supposed to take an independent position. Furthermore, courts normally have the advantage of being able to decide with hindsight, which makes it much easier to look at the effects of regulatory decisions and the strengths of the evidence on which these are based.

An illustrative example of the latter is the prohibition of handheld (mobile phone) calling while driving, which was first introduced in the US but has now spread to many other countries in the world. The aim of this type of legislation was to prevent road-users from accidents. In an interesting and enlightening empirical study, Robert Hahn and Patrick Dudley have shown that the risks and costs of handheld calling while driving probably do not outweigh the benefits, especially if we compare calling to similar potentially distracting activities for drivers that have not been prohibited.⁹⁹ Apart from that, the prohibition of handheld calling might very well send the wrong signal to drivers that using a hands-free device is perfectly safe, while this is certainly not the case. Crash data and numerous empirical studies have shown that it is not so much the use of handheld devices as such that increases the risks of having an accident, but the fact that the conversation distracts our attention.¹⁰⁰ Why should a court, when confronted with a plaintiff challenging a statute like this, not have the opportunity to assess the scientific rationality of the statute?

One possible answer to this last question could be that the scientific rationality of the statute is usually intertwined with the policy decisions underlying the statute. As a result, in cases like this, scientific evidence plays only a supporting role in illustrating what is within the realm of reasonableness. Take the Léger-case. Mister Léger challenged the decision of a doctor at the

⁹⁹R. Hahn and P. Dudley, 'The Disconnect Between Law and Policy Analysis: A Case Study of Drivers and Cell Phones' (2003) *Administrative Law Review* 127–185.

¹⁰⁰See for example US National Safety Council, 'Understanding the Distracted Brain. Why Driving while using Hands-free Cell Phones is Risky Behaviour,' National Safety Council White Paper April 2012. See: <<http://www.nsc.org/DistractedDrivingDocuments/Cognitive-Distracted-White-Paper.pdf>>.

French Blood Agency in Metz who refused his blood donation on the grounds that he had had sexual relations with another man, and that French law excludes blood donations from homosexuals. In this case, the CJEU was not called upon to consider whether there was a dispute as to the efficacy of the measure. Instead, it was asked to survey evidence reflecting the available scientific information to decide whether it was reasonable to apply the measure in its present form. The plaintiff was in fact asking to assess the proportionality of a measure that permanently excludes homosexuals from blood donations. Here, a degree of judicial deference seems to be appropriate. As Bernstein asserts, this partly concerns a question of policy-making. However, is this enough reason for a total avoidance of scientific information? Here, too, we would argue that the court should not be called upon to consider what measure is most appropriate in such a situation. We see no reason, though, why in such a case, national courts would be unable to survey scientific information in order to assess whether the standard of evidence by blood banks is proportionate in relation to the limitation of the fundamental rights of the donors. Is this not exactly what the CJEU would require from national courts? Just suppose that the Dutch proposal for a ban on the wearing of burqas or niqabs had been pushed through parliament by the former coalition government. Should a court then not be allowed to assess the proportionality of that measure in case Muslim women would challenge this law as an infringement of their freedom of religion? In case the answer is affirmative, why should courts in such cases not be allowed to take the advisory opinion of the AD of the Council of State into account, which criticised the evidence-base on which the legislative draft was based?

8. Conclusion

Returning to the research question, we asked ourselves to what extent a proportionality review of laws and regulations by the judiciary requires that courts assess the methodological rigour of the ex ante evaluations conducted during the preparation of laws and regulations or scrutinise the empirical data or scientific evidence used to underpin regulatory decisions.

Our overall conclusion is that the CJEU increasingly finds it necessary to conduct a procedural review of legislation in which it takes ex ante evaluations into account but the court does not go as far yet as to scrutinise the underlying data or the scientific evidence on which consultations and impact assessments rest. The problem with this is that in cases where ex ante evaluations are of poor quality, because the underlying data or scientific evidence are corrupted, this will negatively affect the CJEU's judgment and support the idea that pre-legislative scrutiny is a matter of box ticking. For Dutch courts, the situation is different. They are not yet willing to include ex ante evaluations or empirical

data in a proportionality review of legislation but, interestingly enough, the Advisory Division of the Council of State in its *ex ante* evaluation of legislation occasionally does refer to empirical data and scientific evidence to challenge, for example, the necessity and suitability of certain legislative instruments to fulfil the aims of the legislature. This raises the question: why do courts not use this information?

Courts will have more opportunities to function as regulatory watchdogs and intensify their proportionality review in cases where legislators and regulators are prepared to provide more specific information about the aims of the drafts, the choice of regulatory instruments, and the methods of *ex ante* evaluation they apply. Moreover, as soon as there are going to be more internal quality control mechanisms with regard to legislative draft, such as the Regulatory scrutiny board at the EU-level, courts might in the future rely more on a meta-review by assessing how rigorously such bodies conduct an internal subsidiarity and proportionality review.¹⁰¹ However, the disadvantage of such a purely procedural review is twofold. First, it would send a signal to legislators and regulators that more openness about the policy aims and accountability with regard to methods of *ex ante* evaluation applied in the drafting process might be used against them by courts undertaking a proportionality review. Second, a mere procedural review of the rule-making process might overlook flaws in the empirical data or scientific evidence on which laws and regulations are built, resulting in later regulatory failures.

The Daubert test developed by the US Supreme Court could provide inspiration for the CJEU and for national courts as to how the quality of the legislative facts, empirical data and scientific evidence could be evaluated by the CJEU and by national courts. Simultaneously, Daubert also reveals that in case courts want to review the evidence-base on which laws and regulations rest on a more abstract regulatory level, the judiciary will probably also need to invest more in methods to anticipate future consequences of judicial decisions that are meant to correct or redirect legislative decisions. Nevertheless, we believe that courts could demand more clarity as to how legislators and regulators use facts, empirical data and scientific evidence as a basis for regulatory decisions with regard to the necessity, suitability and proportionality of the measures being taken. This could, for example, be done by requiring that the underpinning of legislative drafts rely more on independent research that is carried out according to accepted methods in the field, while avoiding cherry picking or otherwise trying to steer the outcomes.

¹⁰¹A. Meuwese and S. Gomsian, 'Regulatory Scrutiny or Subsidiarity and Proportionality' (2015) *Maastricht Journal of European and Comparative Law* 490.

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