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TAKING REASONING SERIOUSLY:  
THE ROLE OF COURTS IN ENFORCING  
ARGUMENTATIVE RATIONALITY

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## **Abstract**

The regulation of new technologies, as well as many other areas of our increasingly complex and interdependent societies, involves high uncertainty which grants broad epistemic discretion to the usually unelected regulators. This raises increasing concerns in the public law theory which traditionally requires all authoritative acts to be justified on the basis of *certain* principles mandated by the legislator (or in other words to be non-arbitrary). Political authorities respond to this challenge by the so-called science-based regulation however this approach in practice makes them defer to the advice of obscure and even less legitimate scientific bodies. Worse still, the courts are considered incompetent to review the scientific basis of such decisions and they fail in their duties in their own turn.

In this paper I propose a way out of the latter problem, which was exemplified at least once in the well-known *Pfizer* case of the General Court of the EU. On my reading of the case, the Court reviewed the validity (but not the soundness) of the reasoning of the EU institutions in order to determine whether they had strayed away from the received expert advice arbitrarily. This rigorous review gives the authorities the flexibility necessary in cases of uncertainty yet it held them to a very strict standard of reasoning not to allow them to act arbitrary. Beyond the particular issue, the case shows that the traditional duty to give reasons, if taken seriously, can constrain epistemic discretion and on the other hand can allow the courts to review complex scientific issues without second guessing the political authorities.

## **Keywords**

Precautionary principle; Pfizer; non-arbitrariness; regulation; reasoning

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# TAKING REASONING SERIOUSLY: THE ROLE OF COURTS IN ENFORCING ARGUMENTATIVE RATIONALITY

*Vesco Paskalev*

The High Court of Justice of England and Wales asks the Court what is to be understood by the term ‘monomer substance’. At first sight the reference for a preliminary ruling appears peculiar. One might have expected the question to be addressed to a chemist. However, a closer examination shows that the question can and must be answered with the tools of Community law.

Advocate General Kokott<sup>1</sup>

## Introduction

David Hume noted that “A wise man proportions his beliefs to the evidence” and chooses what is supported by the greater number of experiences.<sup>2</sup> Respectively a wise society would base its fiats on balance of the available competing expertise. Yet it is surprising how the need for balancing of evidence by the public authorities is neglected in legal theory. It is so preoccupied to make political process responsive to citizens (to their will or to their interest), that the need to make it responsive to arguments was ignored. This is easily explained with the legacy of the Enlightenment: we still live with the implicit assumption of scientific certainty, progress and emancipation even as it is becoming increasingly untenable today.<sup>3</sup> On the account adopted in this article, the conclusions of scientific inquiry are matter of judgement on the balance of different competing pieces of evidence. However, having abandoned the vain hope for one undisputable Truth, we have to acknowledge also that balancing is not an ‘objective’ formula or a bright-line rule which will yield The Ultimate Answer. Thomas Kuhn<sup>4</sup> has thought us, science cannot sustain any pretence for universal correctness and validity, and Bruno Latour<sup>5</sup> and Sheila Jasanoff<sup>6</sup> acknowledged that science is neither neutral nor independent of society, politics and culture. Instead, we have to cope with ‘reasonable pluralism’.<sup>7</sup> This applies not only to scientific discovery, but to any other forms of thinking, including balancing, rule-following and even computation. Yet this is not to say that we should abandon them; on the contrary – we should employ formal methods to add rigour to our reasoning and decision-making, to uncover our hidden assumptions and to make our conclusions sensitive to argumentative challenges. We only should accept that the state of persistent controversy (or in the area discussed here persistent uncertainty) is not exception or pathology, but the norm. The acknowledgment that decision-making (and even science-based regulation) is inevitably value-laden requires us to take into account those values: if we know it is futile to straighten our scales, we can instead deliberately tilt them according to the societal goals and values which are at stake.

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<sup>1</sup> Opinion in Case C 558/07 *S.P.C.M. SA, C.H. Erbslöh KG, Lake Chemicals and Minerals Ltd and Hercules Inc. v Secretary of State for the Environment, Food and Rural Affairs*, (ECJ) ECR I-05783.

<sup>2</sup> David Hume, *Enquiry Concerning Human Understanding* (Peter Millican (ed), OUP 2008), p. 80.

<sup>3</sup> For a concise summary of the ‘Enlightenment view’ and discussion of its obsolescence see Gerald F. Gaus, *Contemporary Theories of Liberalism: Public Reason as a Post-Enlightenment Project* (SAGE Publications 2003).

<sup>4</sup> Thomas S Kuhn, *The structure of scientific revolutions* (University of Chicago Press 1970).

<sup>5</sup> Bruno Latour, *We have never been modern* (Harvester Wheatsheaf 1993).

<sup>6</sup> Sheila Jasanoff, *Designs on nature: science and democracy in Europe and the United States* (Princeton University Press 2005).

<sup>7</sup> Gaus, *Public Reason as a Post-Enlightenment Project* (n 3), p. 14.

The present paper will discuss the system of risk regulation in EU as one of reasonable pluralism: system which functions in a state of irredeemable uncertainty yet which is (or ought to be) sensitive to arguments. The system is heavily dependent on science, which is the common response to complexity and uncertainty.<sup>8</sup> As science fails to yield the hard and fast evidence needed to resolve controversies, the stakeholders have to “fight science with science;”<sup>9</sup> thus the decision-making authority is provided with abundant evidence favouring each of the sides which is not conclusive for either position. This leaves the decision-makers in the position to pick and choose. On the other hand, the common good, general will, the election results etc underdetermine the actual measures which are adopted by the various branches on a daily basis. This allows discretion on a scale which renders the principal-agent theory meaningless. Thus the irreducible complexity of governance seems to open space for arbitrary choices, where decision-maker can act as it pleases and justify its choice *ex post*.

In the first part of the paper I suggest that this situation can be remedied if the well-known requirement for the administration to give reasons is taken seriously. Whatever its choice, it should be required to make explicit the whole chain of reasoning, from the most fundamental implicit assumptions to the furthest reaching conclusions. Thus the stakeholders and the critical public will evaluate whether the reasoning that lead to the decision is empirically sound and logically valid. My suggestion is that ‘adding a method to their choices’ would make the decision-making critically dependent on the new information which is made available. On the other hand, it will constrain the decision-makers and prevent arbitrary or strategic decisions. However this will happen only under rigorous watch of the reasoning process. In the second part I discuss how the European Commission adopted a method to its reasoning and how the court enforced it in the *Pfizer* case.<sup>10</sup> It is one primer how the General Court<sup>11</sup> (formerly the Court of First Instance) of the EU required the rigor necessary to assure non-arbitrary argument-sensitive decisions. Although the judges were no experts on the substance of the issue, they reviewed the substantive justification of the decision without second-guessing. Thus, it enforced what I shall call argumentative rationality.

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<sup>8</sup> It is somewhat paradoxical that facing recognizable *scientific* uncertainty we choose to rely on *science* to resolve it. See Marjolein B. A. van Asselt and Ellen Vos, ‘The Precautionary Principle and the Uncertainty Paradox’ (2006) 9 *Journal of Risk Research* 313-336. My guess is that we turn to science because it is an argument-sensitive discipline.

<sup>9</sup> Jane Holder, Maria Lee, and Sue Elworthy, *Environmental protection, law and policy: text and materials* (2nd edn, Cambridge University Press 2007).

<sup>10</sup> Case T-13/99 *Pfizer Animal Health v. Council*. Hereinafter all references to paragraphs will be to this case, unless otherwise indicated.

<sup>11</sup> Hereinafter “the Court” will stand for the General Court while the European Court of Justice will be always referred to with its abbreviation “ECJ.”



## Why Reasons Matter?

There is a deeply rooted tradition of Western political philosophy that political authority, in order to be legitimate, must be not only democratically responsive but also rational and reasonable. In one of its recent incarnations, Philip Pettit's republicanism, authority to interfere in people's lives must be non-arbitrary<sup>12</sup>, and it is so to the extent that it is forced to track the relevant interests and *ideas* of citizens according to their own judgement.<sup>13</sup> Legitimate authorities must be able "to give democratically persuasive reasons for their decisions."<sup>14</sup> A valid reason would be one that is believed to true by most members of the society, otherwise *for the society* it is not a reason at all. This is a demanding condition, because it places on the authorities the burden to take not only the right decisions but to take them for the right reasons (where both decisions and their premises are substantively contestable). The non-arbitrariness condition is applicable also to the 'technical' decisions; they also have to be supported by a chain of propositions which are empirically sound and logically valid. Citizens and stakeholders participate in the democratic process by either contesting such chains or by offering alternative decisions premised on chains of their own construction.

Apart from conferring legitimacy the non-arbitrariness requirement can make the argumentation matter in the decision-making.<sup>15</sup> Even a single individual would act for certain reasons; if acting reasonably means to act for reasons, then a reasonable individual would be able to state her reasons for taking certain action.<sup>16</sup> Thus far, this is a minor constraint on her actions; having reasons need not (though it may) imply conformity to an external normative standard; even a whimsical choice has its reasons – if I eat strawberries with champagne my reason for doing so may be that I like them together and not necessarily because I want to impress someone with my cultured palate or my riches. Only in some cases reasons for actions are based on science or morals – I eat fruits because they are good for my health, or I do not eat strawberries in February because I do not like to damage the environment by having them shipped from the Southern hemisphere. In all cases however, reasonableness implies at least (1) availability of reasons (which the agent can articulate if asked), and (2) some degree of coherence among them.<sup>17</sup> But I will strike you as unreasonable, if I state that I have eaten the first strawberry I was offered because "I like strawberries" yet I deny the second one because "I don't like strawberries." Yet, I can still reasonably deny the second strawberry because "I do not want to appear gluttonous" which does not contradict the reason already stated ("I like strawberries").

The same applies for public authorities: for example they cannot arbitrarily subsidise one strawberry farmer and not the other. Once a regulator has announced a policy to support strawberry producers it binds itself to apply it according to its stated terms. In administrative law this is well-known as the principles of legitimate expectations and of non-discrimination. What is less discussed is that authorities may find themselves constrained also by the reasons for the adoption of the policy. Suppose that the regulator has stated that it would support strawberry farmers because it is committed to promote public health. If later becomes known that strawberries are actually bad for health, the authority may find itself bound to reverse the policy. This would not be the case if the stated reason for the policy was not public health but rural development – the new evidence would have no bearings on

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<sup>12</sup> Philip Pettit, *Republicanism: a theory of freedom and government* (Clarendon Press; Oxford University Press 1997)

<sup>13</sup> *Ibid.*, p. 55.

<sup>14</sup> Philip Pettit, 'Depoliticizing Democracy' (2004) 17 *Ratio Juris* 52-65, p. 53

<sup>15</sup> Elsewhere I shall demonstrate by formal models that there is more than semantic link between reason (as capacity) and reason (as premise for action).

<sup>16</sup> Reasons for action are the beliefs on the premises one may consider relevant in deciding whether to take the action.

<sup>17</sup> Coherence is not a normative requirement, yet a reason that is cancelled by another reason is no reason at all.

the policy at all. To generalise, the authoritative decisions are path-dependent, and the path is being set not only by the earlier decisions, but also by the reasons they were premised on.

A telling example how such innocuous statements can matter was provided by a recent authorisation of a genetically modified potato for cultivation in Europe.<sup>18</sup> There was vigorous controversy on all aspects of the issue, but eventually it boiled down to debate on two relevant premises – whether the potato may confer resistance to certain antibiotics to consumers through the food chain *and* whether these antibiotics are actually (or potentially) used in human medicine. According to the statement of the European Food Safety Authority (EFSA) it was very unlikely that the cultivation of the potato may confer antibiotic resistance to humans and the antibiotics affected (kanamycin and neomycin) were not important for human and veterinary medicine anyway. Thus both premises were cumulatively satisfied and the potato was in train for authorisation. In the meantime however the World Health Organisation (WHO) published a report identifying these antibiotics as very important. Thus EFSA came under pressure to reverse its opinion. It actually did not; instead it tried to reshape the initial decisional framework stating that the premises should not be cumulatively but alternatively available. But this move took a big toll on its credibility, EFSA was severely criticised by the EU authorities and citizens. More importantly, on this ground the authorisation decision is now being challenged by five member states in the General Court. Should the Court rule for the applicants it will make a huge step toward making the Union non-arbitrary authority. In any event, this example illustrates how the stated decisional method may constrain its author and how the new evidence may become factor for the decision, outside of decision-maker's control. Note that the non-arbitrariness requirement has two sides: first, statements of reasons are commitments affecting future acts, and second, the use of reasons makes process sensitive to arguments.

But if we want any of this to be more than a theoretical construction, we must seek institutions for epistemic vigilance – they are to *make* the decisions sensitive to arguments, i.e. they have to identify the commitments, to expose the ignoring of evidence and to punish violations. This is done by the adoption of rigorous reasoning methods and opening the process to argumentative challenges on the substance. Many of the established institutions and principles of public law can be interpreted as methods to enforce discipline of reason.<sup>19</sup> Beyond the very duty to give reasons such function is performed by judicial review, ministerial oversight, transparency and accountability, public inquiries, impact assessments, cost-benefit analysis and generally, any criticism in the public sphere. Most of the institutions of contemporary democracy, intently or not, make the decision-making more sensitive to arguments and thus less arbitrary.

My claim it that this argument holds for all public authorities including the administrative regulators even though they usually are agency which are (or at least perceived) as a singular decision-maker. Indeed, they always have very broad margin both to identify the set of premises relevant for the decision and to assess them with regard to the available evidence. However, once this is done in a policy paper, guidance or another 'soft law' instrument, the regulator is constrained by its own statement. It is under pressure to stick to its words. Certainly, this constraint is effective only when it is costly for the decision-maker to forswear its earlier public statements of reasons.<sup>20</sup> When it needs to interact with the surrounding environment this would often be the case; it is the vigilance of the others that makes the statements of reasons matter. This is especially the case with the EU institutions,

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<sup>18</sup> For a detailed study of the case see Vesco Paskalev, 'Can Science Tame Politics: The Collapse of the New GMO Regime in the EU' (2012) 4 *European Journal of Risk Regulation*.

<sup>19</sup> Pettit's classic model is that of premisewise voting, see Philip Pettit, 'Deliberative Democracy and the Discursive Dilemma' (2001) 35 *Noûs* 268-299. Elsewhere he has suggested also use of straw-poll and sequential voting but none of this is actually implemented anywhere. His practical proposals are various "contestatory" institutions allowing citizens to subject the authoritative decisions to public valuations see Pettit, '*Depoliticizing Democracy*' (n 14).

<sup>20</sup> It may lose credibility, be publicly censured by the overseeing authority, its directors fired or lose bonuses or promotions; its decisions may be contested by stakeholders or even reversed by administrative or judicial review.

when no institution possesses full legal authority on any issue and even if it does it constantly seeks the cooperation of the others.

Thus far I have argued that reasons ought and do matter in public decision-making. When this is so, rational actors would have a special interest to use reasons in order to influence the decisions. The use of arguments to influence the decision-making process I shall call argumentative rationality.<sup>21</sup> Argumentative rationality must be distinguished from instrumental rationality. The latter is a broader term and refers to the use of practical reason by actors in order to choose the action which is the best means to achieve their ends. Strictly speaking, argumentative rationality is a subspecies of instrumental rationality, where the means are arguments and the end is persuading the other actors in order to secure certain preferred collective decision. Argumentative rationality is not always an effective means to this end but in two cases it is: either when other agents are open to be persuaded, or in cases where the decision-making process is deliberately designed to be sensitive to arguments. The former corresponds to what deliberative democrats call ideal speech situation and the present paper is not concerned with it. It will be concerned only with the latter case where the decision-making itself is geared in such a way that the arguments brought forward make difference, despite the stubbornness or selfishness of the agents. My claim is that public exchange of arguments, i.e. discourse in the public sphere, may be an independent factor for the behaviour of the rational agents. A vigorous debate is going on in the current scholarship whether arguing or bargaining prevails in international negotiations and especially in the EU, but I do not need to take side in this paper.<sup>22</sup> Instead I shall take the modest position that arguments matter at least *ceteribus paribus*, and will be interested how they can be made to matter more. This is the perspective of ‘discursive institutionalism’ whose leading proponent cautiously warns that discourse does not preclude power and we should not assume that deliberation can trump manipulation.<sup>23</sup>

On this approach the agents are considered to be not only rational, but *reflectively rational* – while they pursue their self-serving goals in accordance to their beliefs, they also “think about their thoughts, reflect upon their actions, state their intentions, alter their actions as a result of their thoughts about their actions ... and change their minds in response to persuasion by others regarding what they are thinking, saying and doing.”<sup>24</sup> While this approach may be applied to all areas of decision-making, it is particularly appropriate for regulation or risk, because the decisions in that area are by definition taken in a state of uncertainty and most susceptible to change upon new information. The pertinence of the concept of reflectively rational agents (or reflective agents for short) was illustrated during the volcanic ash crisis in April 2010, when all flights in northern Europe were cancelled for about a week, leaving millions of passengers stranded abroad. All of the agents involved had their self-serving goals, yet their beliefs and preferences were not fixed; they developed as new information was made available. Thus, even though the air companies appeared to prefer to fly and avoid losses, it would be inaccurate to say that their interest or preference was to fly and to risk passengers’ lives because any accident would bring enormous losses to them as well. Nor could the interest of the passengers be

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<sup>21</sup> The paradigmatic example here is the jury trial where the parties use argument to secure the outcome that suits them best. It may appear that the second case depends on the availability of at least minimal number of persuadable participants but this is not necessarily so.

<sup>22</sup> For this debate see for example Thomas Risse, ‘Let’s Argue!’: Communicative Action in World Politics’ (2000) 54 *International Organization* 1-39, Cornelia Ulbert, Thomas Risse, and Harald Müller, ‘Arguing and Bargaining in Multilateral Negotiations,’ *Center for Transnational Relations, Foreign and Security Policy (ATASP)* (2004). For the futility of the debate see Nicole Deitelhoff and Harald Müller, ‘Theoretical paradise – empirically lost? Arguing with Habermas’ (2005) 31 *Review of International Studies* 167-179.

<sup>23</sup> Vivien A Schmidt, ‘Taking ideas and discourse seriously: explaining change through discursive institutionalism as the fourth ‘new institutionalism’’ (2010) 2 *European Political Science Review* 1-25, p. 21.

<sup>24</sup> *Ibid.*, p. 17. This is a significant departure from the classic instrumental rationality, which takes agents’ goals for granted, and as unchangeable during the interactions. Schmidt uses the term sentient agents, but I find it a bit esoteric and prefer reflectively rational or just reflective.

taken for granted – certainly their paramount concern was to remain alive, yet they also were desperate to fly home. Finally, the regulators were responsible mainly to avoid risks, yet they also did not prefer to keep the sky closed for weeks just to be on the safe side. All agents reflectively changed their preferences during the interactions in response to the new evidence.<sup>25</sup>

Argumentative rationality must be distinguished from what political scientists call rhetorical action, or “strategic use of norm-based arguments.”<sup>26</sup> The latter is another sub-species of instrumental rationality which is used in “institutional environments [where] political actors are concerned about their reputation as members and about the legitimacy of their preferences and behaviour.”<sup>27</sup> In such cases agents are required to justify their claims on the ground of certain common values, i.e. they may advance certain interest only if it is represented as a common one while on the other hand they can defeat opponents by showing that they fail to do so. While the claims used in rhetorical actions may be permitted or not with regard to certain common values, argumentative rationality allows them to be judged in terms of logical validity or invalidity, persuasiveness and coherence.

Another subtle distinction that needs to be done is between argumentative rationality as defined here, and argumentative rationality in the sense in which it is used by Thomas Risse.<sup>28</sup> He uses it as equivalent to Habermas’s communicative action; argumentatively rational agents in that account have the specific goal to reach common understanding; they are open to persuasion and power recedes in the background.<sup>29</sup> The sense in which I use argumentative rationality is much less laden and neither of the two is necessary. Nevertheless, on both Risse’s and mine version, the agents are reflective, i.e. they take into account new information which may affect their beliefs and goals. Here the goal of the agents is only to persuade others in the general social choice case, and in the particular case of participation in regulatory processes - to provide the public authorities with convincing reasons for action. The agent may succeed if he provides reasons that appear to pertain to the public interest and the truth, and in that sense it is a reason that could be accepted as valid by all. However, this may be only the means to achieve selfish ends, and not goal itself as it is for Habermas and his followers. I believe this is important relaxation of the ideal speech situation and in my view even if agents are not honest truth-seekers arguments can matter.

An example may expose the subtle differences between rhetorical action, argumentative rationality (in my sense) and communicative action. Think of an Italian politician who proposes a restriction on pasta import on the ground that pasta is not merely food, but an expression of the Italian culture, which is endangered by cheaper imitations coming from other members of the EU. If his real concern is to protect domestic industry from competitors we have a classic example of rhetorical action. As overt protection of domestic industry violates the free movement norms, such proposal cannot be legitimately defended, therefore the politician substitutes it with permissible proxies. An example of argumentative action in the sense adopted here would be the case when the same politician provides some statistical information that the pasta production in Italy is decreasing to the point of disappearance and that is why an intervention to save it is necessary. It would not matter if the agent actually cares for local culture or for vested business interests, or whether he is ready to be persuaded if contrary evidence is present. What distinguishes argumentation from rhetoric is that the reasons given are subject to verification and refutation. Finally, we would have an example of communicative action in the Habermasian sense if this politician is himself willing to give up his concerns for domestic producers if faced with counter-evidence that neither pasta, nor its producers are endangered.

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<sup>25</sup> Note that in such circumstances the principal-agent account cannot make any sense at all.

<sup>26</sup> Frank Schimmelfennig, ‘The Community Trap: Liberal Norms, Rhetorical Action, and the Eastern Enlargement of the European Union’ (2001) 55 *International Organization* 47-80, p. 47.

<sup>27</sup> Ibid.

<sup>28</sup> Risse, ‘Let’s Argue!’: *Communicative Action in World Politics*’ (n 22).

<sup>29</sup> Ibid, p. 7.

When the latter is the case we are in ideal speech situation and it is likely that agents would reach consensus. In my view genuine truth-seeking, persuasion and agreements do happen<sup>30</sup> yet they are hardly the norm, hence the common criticism that deliberative democratic accounts are utopian. That is why I propose a thinner version of argumentative rationality as seeking to provide reasons for action and not to reach consensus.

Thus far I have argued that reasons ought and sometimes do matter in public decision-making. When this is so, rational actors would have a special interest to use reasons in order to influence the decisions. For the purposes of this paper I shall call the use of arguments to influence the decision-making process argumentative rationality.<sup>31</sup> Argumentative rationality is a subspecies of instrumental rationality, where the means are arguments and the end is persuading the other actors in order to secure certain preferred collective decision.

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<sup>30</sup> See for example the seminal article Christian Joerges and Jurgen Neyer, 'Transforming strategic interaction into deliberative problem-solving: European comitology in the foodstuffs sector' (1997) 4 *Journal of European Public Policy* 609-625, more recently Jeffrey Lewis, 'Strategic Bargaining, Norms and Deliberation' in Daniel Naurin and Helen Wallace (eds.) *Unveiling the Council of the European Union : games governments play in Brussels*, Palgrave Macmillan (2008) and also Jeffrey T. Checkel, 'International Institutions and Socialization in Europe: Introduction and Framework' (2005) 59 *International Organization* 801-826 and the following articles in the same volume.

<sup>31</sup> The paradigmatic example here is the jury trial where the parties use argument to secure the outcome that suits them best. It may appear that the second case depends on the availability of at least minimal number of persuadable participants but this is not necessarily so.

## Enforcing Discipline of Reason

In the previous section I have postulated the non-arbitrariness as condition for legitimacy of the acts of public authority (which is amply justified by Philip Pettit). I argued that this condition makes reasons matter, and in turn, that the reliance on reasons constrains the authority and makes it sensitive to arguments. For this to happen in real life however, I suggested that first authorities must have stated methods for reasoning, and second, the others must be vigilant whether they apply them. Now I show how soft law is such method and how the court can enforce it. In the well-known *Pfizer* case the Court reviewed the reasoning of the EU institutions with regard to the method announced in a Communication of the European Commission. In particular, it assessed whether certain array of available evidence could justify certain the conclusion of the Council. Thus, it reviewed the quality of epistemic base of the decision and the validity of the conclusions drawn from it.

### *Precautionary Principle as Empowering Principle*

The precautionary principle as understood by the European Commission provides an instructive example for a rigorous method for discipline of reason. Originating in environmental law now it is understood to be a general principle of Union law.<sup>32</sup> On its face, this is a broad principle which *empowers* the decision-makers to take measures for protection even if the actuality of the danger is uncertain.<sup>33</sup> Such seemingly was its initial understanding by the European Court of Justice (ECJ) which used to be deferential to the Union institutions. In the previous landmark case – *FEDESA* – ECJ reviewed only “whether the measure in question is vitiated by a manifest error or misuse of powers, or whether the authority in question has manifestly exceeded the limits of its discretion”<sup>34</sup> and it applied this test with a ‘light touch.’<sup>35</sup>

From the fact that the countries were unable to agree on the assessment of evidence the Court assumed that evidence was inconclusive and this had unleashed the Council to do as it pleased. Thus, in the parlance adopted here, the ECJ did not impose any reasoning methodology to the authorities. Many commentators commended this approach; interestingly for Fisher claimed that instead of being controlled by the political principal, the decision-maker should be “insulated from the mainstream political process, which is over-responsive to particular political interests.”<sup>36</sup> Thus, *in lieu* of trust in objectivity, the trust in such deliberative decision-making process should be derived “from human capacity for civic virtue and public reason.”<sup>37</sup> This claim, in principle, agrees with the argument developed in the previous section. Fisher’s argument from practical reasoning finds normative support in the republican theory. The call for deliberation and insulation of the decision-maker apparently corresponds to Pettit’s call for depoliticization<sup>38</sup> and to his argument that decisions should embody collective reason rather than public opinion.<sup>39</sup> Fisher’s argument is not based on the republican theory and does not discuss how public reason is to be achieved. On the contrary, she explicitly contrasts the suggested ‘deliberative’ approach to the application of stricter methodology which she associates only

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<sup>32</sup> In *Pfizer* see para 114 and 183 and the list of cases referred to in para 115.

<sup>33</sup> See Principle 15, UN Declaration on Environment and Development (Rio Declaration), <[www.unep.org/Documents.multilingual/Default.asp?DocumentID=78&ArticleID=1163](http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=78&ArticleID=1163)>, accessed on 12 February 2011.

<sup>34</sup> C 331/88 *FEDESA and Others v. Council*, (ECJ), para 8.

<sup>35</sup> Paul P Craig and Gráinne De Búrca, ‘*EU law: text, cases, and materials*’ (Oxford University Press 2008), p. 570.

<sup>36</sup> Elizabeth Fisher, ‘*Risk regulation and administrative constitutionalism*’ (Hart 2007), p. 31.

<sup>37</sup> *Ibid*, p. 35.

<sup>38</sup> Pettit, ‘*Depoliticizing Democracy*’ (n 14).

<sup>39</sup> See especially Pettit, ‘*Deliberative Democracy and the Discursive Dilemma*’ (n 19).

with the principal-agent paradigm.<sup>40</sup> This is unfortunate, because if the argument elaborated above is correct non-arbitrary decisions can be attained only through use of some method imposing discipline of reason.

### ***Precautionary Principle as Bright-line Rule***

Feeling the need to deal with the precautionary discretion the Commission published a *Communication from the Commission on the Precautionary Principle*.<sup>41</sup> The Communication is not a binding instrument, nevertheless it represents a commitment by the Commission to abide to it itself.<sup>42</sup>

According to the Communication risk regulation consists of three elements – risk assessment, risk management, and communication of risk.<sup>43</sup> Risk assessment is considered to be a matter of scientific expertise, while risk management is a matter of political choice.

In the parlance adopted here this would allegedly provide a method for discipline of reason and should be welcomed. However the method appears to be too rigid and its core is the mechanical division of risk assessment and risk management. The Communication is very clear that precautionary principle guides risk management only.<sup>44</sup> One reason to circumscribe it in this way was the pursuit of scientific legitimacy by reliance on an objective and independent source of knowledge. Note that scientific objectivity is understood as firm exclusion of social and political factors which are supposed to be taken into account by the political authority in the distinctively different phase of risk management. Ideally, this division into discrete tasks should still allow the administration free choice to act or not to act in the face of risks, yet it should not allow the adoption of arbitrary decisions as the discretion phase is reached only after certain triggering conditions are satisfied according to the ‘independent science’.

Thus, only after satisfying itself that there is “a scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question” the public authority is unleashed to choose whether to take precautionous action.<sup>45</sup> The action itself should be subject to cost-benefit analysis as well as the other applicable principles of EU law as proportionality, non-discrimination, etc.<sup>46</sup> Public health should have

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<sup>40</sup> See Fisher, *Risk regulation and administrative constitutionalism* (n 36), p. 221. The view advocated here is that strict separation of risk assessment and risk management is just one possible methodology and while it is too dependent on quantification and therefore often unattainable and counterproductive, other methods of discipline of reason are not only possible but necessary.

<sup>41</sup> Communication from the Commission on the Precautionary Principle, COM (2000) 1, 02.02.2000, [http://ec.europa.eu/dgs/health\\_consumer/library/pub/pub07\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf), accessed on 11 May 2012, hereinafter “the Communication.”

<sup>42</sup> “The aim of this Communication is to inform all interested parties ... of the manner in which the Commission applies or intends to apply the precautionary principle when faced with taking decisions relating to the containment of risk,” *ibid.*, p. 9. It is worth noting that as the Commission has monopoly in proposing legislation in the EU and therefore constraining itself would in effect constrain all institutions. Further, the ECJ tends to apply the constraining principles of EU even more stringently when reviewing actions by MS so the Communication would potentially have much broader impact.

<sup>43</sup> This division is not novel, it is common practice worldwide.

<sup>44</sup> However the Communication distinguished precaution from prudence, with the former being part of risk management while “the prudential approach is part of risk assessment policy which is determined before any risk assessment takes place ... it is therefore an integral part of the scientific opinion delivered by the risk evaluators”, *ibid.*, p. 13. This seems to be completely ignored in practice.

<sup>45</sup> Note that according to the Communication, even when the triggering conditions are met the precautionary principle does not oblige the institutions to take action on the safe side, but is only allowed to do so if it so chooses.

<sup>46</sup> Communication, p. 18.

greater weight than economic considerations (but only in this stage).<sup>47</sup> If the conditions of what we may call precautionary discretion are met, the precautionary action is expected to be judicially reviewed only for manifest error, misuse of power or exceeding the scope of discretion, which used to be a low-intensity test until 2002 when *Pfizer* was decided.

The risk analysis framework established by the Communication ignored what Weimer calls the “social embedment of scientific reasoning” and its usual uncertainty in the areas of risk. Apparently the Commission called the Enlightenment view to provide scientific legitimacy to its regulatory power. There are three palpable problems with such objectivist view. First, the application of norms reliant on conclusive assessments is thwarted when science fails to deliver them. Science often cannot provide any probability of the risk assessed yet some probability estimate is needed to trigger the more flexible risk management. Nor is science always able to estimate the degree of its uncertainty about the results. Second, if the risk assessment and risk management phases remain truly discrete, the allegedly political risk management decisions will be often pre-determined by obscure expert risk assessors. The seemingly functional division of labour actually brings about an enormous shift of decision-making power. Thus, the employment of independent expertise fails to confer scientific legitimacy to regulatory decisions yet it deprives political actors from choice. Finally, while the objectivist view explicitly excludes legitimate considerations from the assessment, many implicit value-laden assumptions still pervade them.<sup>48</sup> Certainly “if science is perceived as objective and neutral, then all the “extra-scientific” considerations will necessarily appear as secondary, because they are interest guided or arbitrary or simply not “fact.”<sup>49</sup> If some premises are granted the status of “hard and fast” then it is inevitable that the others will be “softened” and easier to ignore.<sup>50</sup> The last problem seemingly was noticed by the European Council which agreed with the Communication but called for greater role of deliberation and values.<sup>51</sup> As it will be seen below, the Court got the message.

There is one further reason why risk assessment cannot be left to science only: the principle of scientific parsimony. It is generally considered that in case of doubt a diligent scientist should apply Occam’s Razor<sup>52</sup> i.e. she should presume non-existence of certain causal effect or untoward consequences. She would certainly state the limitations of current knowledge, yet if she is to draw a conclusion it is likely to contain only what is certain or at least probable and the variety of effects that are merely possible (as well as the disclaimers) are likely to be left out.<sup>53</sup> Thus science and regulation

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<sup>47</sup> Ibid., p. 20.

<sup>48</sup> Even Cass Sunstein, notorious as a critic of precautionary principle and advocate of cold-blooded cost-benefit analysis Cass Sunstein, *Risk and reason: safety, law, and the environment* (Cambridge University Press 2002).

<sup>49</sup> Maria Weimer, ‘Legitimacy through Precaution in European Regulation of GMOs? From the Standpoint of Governance as Analytical Perspective’ in Christian Joerges and Poul F Kjaer (eds), *Transnational Standards of Social Protection: Contrasting European and International Governance*, vol. 5 (ARENA/RECON 2008), p. 160.

<sup>50</sup> This is a common problem of all partial quantifications. M. Livermore recently emphasised the strenuous relationship of quantification and values: emphasis on non-quantified factors undermines consistency, transparency of analysis and increases discretion but failing to take these factors into account unduly ignores potentially important consequences merely because of our epistemological limitations (See Michael A Livermore, ‘A Brief Comment on “Humanizing Cost-Benefit Analysis”’ (2011) 3 *European Journal of Risk Regulation* 13-17, p. 15).

<sup>51</sup> Fisher, *Risk regulation and administrative constitutionalism* (n 36), p. 228.

<sup>52</sup> This is the popular name of the methodological principle, initially formulated by Duns Scotus in 13c AD also known as law of Parsimony, “which prohibits, without a proven necessity, the multiplication of entities, powers, principles or causes” William Hamilton, *Discussions on philosophy and literature, education, and university reform* (Harper & Brothers 1856), p. 580. It is still dominating scientific reasoning today: “nature may or may not favour simplicity, but we should certainly do so – simply as a matter of rational procedure. ... [this is] a methodological tool of inquiry.” Nicholas Rescher, *Aesthetic factors in natural science* (University Press of America 1990) Nicholas Rescher, *Aesthetic factors in natural science* (University Press of America 1990), pp. 3-4.

<sup>53</sup> Fisher gives a very pertinent example of the Southwood Working Party, which was an advisory group that gave early assessment of the risk related to the BSE. It stated that they were operating in uncharted waters and *at that time* the disease was not known to be transferable to humans and that was way further research was necessary. This was taken by



are guided by different decisional principles and the principle of the one may lead to inadequate conclusions if applied to the other.<sup>54</sup> When the two are rigidly separated and compartmentalised to the respective epistemic community there will often be negative collisions: scientific parsimony will often prevent political precaution from coming into play at all.

The problems would be avoided if two distinct conclusions from the *same evidence* can be drawn; if it is insufficient we may have to suspend our epistemic judgement, nevertheless we still can make a practical judgement if we must decide on a policy.<sup>55</sup> Apparently the job of the scientists is to make only epistemic judgements and of the regulators to make practical ones. Both judgements are to be premised on the same evidential basis, while the reasoning methodology may be different. The trouble with the Communication's approach is that the compartmentalisation of the two judgements into risk assessment and risk management makes the practical judgement premised on the epistemic one. On the view advocated here, the risk managers are to engage with the factual premises themselves, i.e. to balance the evidence and this seemingly is what the Court in *Pfizer* allowed them to do.

In the preceding section I have argued that non-arbitrariness requires public authorities to be constrained by the arguments and evidence and this may appear to contradict to the argument here that they should have the liberty to assess the evidence differently. Yet the contradiction is only *prima facie*. Precisely because decision-makers can be constrained by the evidence placed in the public domain they are to remain responsible to draw the practical conclusions from it. But if scientific evidence is central for regulation of certain issue then it should be subjected to the usual mechanisms of accountability and criticism in the public sphere and not black-boxed into obscure expert bodies. In turn courts must review the evidence the public authorities relied upon.

### ***The Precautionary Principle as Balancing Formula***

The issue in *Pfizer* was a Council decision to prohibit the use of virginamicin, an antibiotic used as growth promoter in pig and poultry farming throughout Europe for the past 30 years. Yet a concern was growing that excessive antibiotic use promotes development of antibiotic resistance which might be transferred from animals to humans. Virginamicin is not used in human medicine, but it belongs to the group of streptogramins, and there are several other antibiotics in this group, which are or may be used; it is their efficacy that would be endangered if virginamicin-resistance is transferred to humans. However, there was no conclusive evidence that the continuous use of virginamicin as growth promoter in farming presents *actual* risk of transfer of such resistance and respectively that there is any risk for human health. Pfizer which had been duly authorised to produce virginamicin, claimed that the available evidence did not justify its prohibition, and that the precautionary principle does not warrant adoption of a zero-risk policy. The EU institutions claimed that there is enough evidence that potential risk exists, even though they agreed that there is no evidence for actual danger for the time being and also that precautionary principle does not justify zero-risk policy.

The process which led to the ban was initiated by Denmark, which decided to prohibit virginamicin use in farming on its territory. It invoked a safeguard clause in the applicable directive, which allowed it to take such action if there is 'new information' or 'reassessment of existing information' that an EU-authorised product constitutes danger to animal or human health.<sup>56</sup> The Commission referred the information supporting the Danish ban to the Scientific Committee on Animal Nutrition (SCAN), a

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the risk managers as a conclusion that probability of the risk is low (Fisher, '*Risk regulation and administrative constitutionalism*' (n 36), p. 80).

<sup>54</sup> In different context Fred Schauer noted that "Slight support (or weak evidence) ought not to be good enough for scientists, but is often sufficient for law." Frederick Schauer, 'Can Bad Science Be Good Evidence: Lie Detection, Neuroscience, and the Mistaken Conflation of Legal and Scientific Norms' (2010) 95 *Cornell Law Review* 1191, p. 1208

<sup>55</sup> See Resnik, p. 341, emphasis added.

<sup>56</sup> Article 11 of Council Directive 70/524/EEC concerning additives in feeding-stuffs, OJ L 270 from 14.12.1970.

permanent advisory body. Pfizer also submitted its observations to SCAN and had discussions with the Commission officials. On 10 July 1998 SCAN issued its opinion where it considered the information provided and concluded that “there was no new evidence ... to substantiate the transfer of [antibiotic] resistance [to] compromise the future use of therapeutics in human medicine” and also that “the data provided do not justify the immediate action taken by Denmark to preserve streptogramins as therapeutic agents of last resort in humans.”<sup>57</sup> Nevertheless, the Commission proposed to ban the use of virginamicin and three other antibiotics as growth promoters.<sup>58</sup> The draft was considered by a comitology committee (Standing Committee for Feedingstuffs) which failed to reach a decision. Thus, the regulation was referred to the Council which adopted it (17 December 1998). Pfizer filed an application for its annulment.

The central controversy was on the fact that the EU institutions had disregarded the opinion of the scientific advisory body - SCAN - and relying on the precautionary principle adopted the ban on the ground of what was acknowledged to be inconclusive scientific evidence. There was some evidence for potential risk and abundant evidence from the long harmless practice, so that the institutions had to balance between arguments for and against the ban, while the Court reviewed if that balancing was done correctly with surprising rigour. In effect it “peer-reviewed” the assessments of the institutions in order to decide whether they had proper evidential basis to draw a conclusion that they can take precautionary action.

What provoked this new rigour were, in my view, the special circumstances of the case: there was well-established practice to use antibiotics as growth promoters and no case of actual harm to animal or human health. Thus, the unrestrained discretion of institutions to act as they choose which was allowed by Even though the precautionary principle on its generous interpretation as per *FEDESA* would sustain a ban, public authorities should not destroy so well-established economic activity and abolish the predominant farming practices<sup>59</sup> without sufficiently substantiated argumentation. It would be unpredictable, populist, capricious, superstitious and most importantly it would violate the non-arbitrariness principle.

Apparently the other thing that brought about change in the jurisprudence was that the Commission itself had moved to constrain itself with the Communication. Even though the ban was adopted (and the appeal was lodged) before the Communication was issued, the case was decided after it, and the Court relied on it in its reasoning. It explicitly noted that the Communication “may be taken as a codification of the law as it stood at the time.”<sup>60</sup> In the phrase adopted here, with the Communication the Commission adopted a method for collective reasoning, and subsequently the Court controlled whether its decisions were up to its own method.

The first striking thing in this judgement is its sheer length – it is 519 paragraphs long, well above the 50 paragraphs of *FEDESA*.<sup>61</sup> The second and more important thing is that the Court reviewed the scientific information that was presented by the parties in the run up to the ban in terms of availability and comprehensiveness of evidence and of validity of the inferences drawn from it. The Court did not

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<sup>57</sup> *Opinion of the Scientific Committee for Animal Nutrition on the immediate and longer-term risk to the value of Streptogramins in Human Medicine posed by the use of Virginamicin as an animal growth promoter (produced at the request of the Commission in response to the action taken by Denmark under a safeguard clause to ban virginamicin as feed additive)* (10 July 1998), [ec.europa.eu/food/fs/sc/scan/out14\\_en.html](http://ec.europa.eu/food/fs/sc/scan/out14_en.html), accessed on 11 May 2012.

<sup>58</sup> Another banned antibiotic was bacitracin zinc. This was the reason for another appeal against this regulation, in *Alpharma Inc. v. Council*, T 70/99 (General Court) [2002], II-03495. The judgement in this case was delivered on the same day as Pfizer and most of the reasoning in the two opinions was identical.

<sup>59</sup> The Court recognised them to be “legally protected positions,” see below.

<sup>60</sup> Para 149.

<sup>61</sup> See note 34.

shy away from this task, but plunged in what seems to be quality control of scientific reasoning.<sup>62</sup> As the dispute was on what the proper *assessment* of the risk was, the Court explicitly announced that it will examine whether “the Council was wrong on conclusion of a risk assessment that was not properly conducted”<sup>63</sup> before evaluation of its management of that risk. The third important thing in this judgement is the elevated role that the Court awarded to the scientific advisory bodies. It is impressive that the Court dismissed Council’s defence that SCAN was Commission’s advisor and the Council was in no way bound by its opinion.<sup>64</sup> The Court held that EU institutions **must** seek advice from independent advisors, which is not new,<sup>65</sup> but also that they will be held responsible to justify their deviations from that advice. Finally, it is not immediately obvious, but the Court abandoned the clear distinction between facts and value that the Communication was at pains to establish, and allowed the assessment of the facts to be tinted by the values at stake.

This was the first deviation from the Communication. In Court’s understanding of the method, values could be taken into account in risk *assessment*. However, it provided guarantees against arbitrariness – institutions were required to collect all evidence and to take advice from independent experts. Yet this expertise should not prejudice the practical judgement of the political authorities. In order to preserve responsibility to whom it belongs the Court allowed them to diverge from the recommendations on the condition that they can justify it on “sufficiently reliable and cogent”<sup>66</sup> alternative information. To maintain the latter guarantee meaningful the Court itself would engage in rigorous review of the available epistemic base and the conclusions drawn from it.

By allowing values at stake to affect the assessment of evidence the Court turned Communication’s bright-line rule into open-ended balancing.<sup>67</sup> Even though it formally maintained the distinction between risk assessment and risk management, it emphasised that the non-scientific factors at stake should be taken into account when the level of unacceptable risk is being determined:

the authority may take account, inter alia, of the severity of the impact on human health were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge.<sup>68</sup>

The Court was aware that in cases of risk regulation evidence will be often inconclusive, that is why it held that, having collected the best available expertise,

the competent public authority must therefore weigh up its obligations and decide either to wait until the results of more detailed scientific research become available or to act on the basis of the scientific information available. Where measures for the protection of human health are concerned, the outcome of that balancing exercise will depend, account being taken of the particular

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<sup>62</sup> This is not uncharacteristic for the EU judicature; speaking about the pre-Pfizer cases Fisher notes that “the concern of both courts was on the quality of reasoning rather than on the accuracy of factual analysis” (Fisher, ‘Risk regulation and administrative constitutionalism’ (n 36), p. 223). *Pfizer* fits in this process-perfecting tradition well, the only difference was that here the Court took its quality control mission seriously.

<sup>63</sup> Para 110.

<sup>64</sup> Para 193-195.

<sup>65</sup> There is a number of cases where courts held that decision-makers are obliged to seek advice, including to seek scientific advice when expertise is needed – see *Angelopharm GmbH v Freie Hansestadt Hamburg*, Case C-212/91 (ECJ) ECR I-00171 for one.

<sup>66</sup> Para 162.

<sup>67</sup> Balancing as judicial technique usually refers to weighing and choice between two conflicting and incommensurate values which are equally important so that the outcome cannot be given in advance (in rules) but is to be decided with regard to the particularities of the case. Notwithstanding this, it is essential for balancing that the choice is to be made in non-arbitrary way, i.e. following some formula, structure or any other relatively autonomous criteria for correctness. In this case the balancing was done by the Union institutions, but the Court reviewed it to ensure non-arbitrariness.

<sup>68</sup> See para 152-154.

circumstances of each individual case, on the level of risk which the authority deems unacceptable for society.<sup>69</sup>

In turn when reviewing the weighing by the institutions the Court should take account “first of the seriousness of the repercussions ... and second, of the results of the scientific research.” Figuratively speaking they have to balance the evidence with scales tilted according to values at stake.

Yet by reinterpreting the precautionary principle as open-ended formula the Court did not issue a blank check to the EU institutions to make arbitrary risk assessments. On the contrary, it placed on them heavy burden to justify their decision with scientific reasoning of highest quality.<sup>70</sup> The Court went a long way to make authorities engage with assessment of the evidence and thus to remain fully responsible for the decision. It was well aware of the danger of allowing the “other” factors to undermine the scientific legitimacy and that is why it emphasised that when the institutions are granted broad discretion to affect legally protected positions<sup>71</sup> “the guarantees conferred by the Community legal order in administrative proceedings are of even more fundamental importance.”<sup>72</sup> With its lengthy judgement the Court was struggling to re-establish these guarantees and enforce a method to institutions’ reason.

The first guarantee was that the “competent public authority *must* ... entrust a scientific risk assessment to experts who ...will provide it with scientific advice”<sup>73</sup> and they must obtain scientific advice even if the secondary legislation has not specifically provided so. The rationale of this requirement is apparently the information provided by the advisors, once in the public domain, would make a difference. The Court went on to hold that the institutions “must ensure that their decisions are taken in the light of the best scientific information available and that they are based on the most recent results of international research”<sup>74</sup> and also that “the institutions were in a position to examine carefully and impartially *all* relevant evidence in a particular case.”<sup>75</sup> The Court sought to perfect not only the decision-making process but the epistemic base of the decision and to enforce methodology for rigorous reasoning.

It is worth to consider the role of scientific advisors which is accorded by this test. Even though SCAN was advisory body *of the Commission*, the Court found that “the Council was wrong to maintain ... that the assessment made in the SCAN opinion could not have any influence on its own position [because it] did not ask for an alternative risk assessment to that carried out by SCAN but that it endorsed the position adopted by the Commission ... and did so on the basis, *inter alia*, of the SCAN opinion [therefore] the risk assessment carried out in this case by the Commission on the basis, *inter alia*, of the SCAN opinion also binds the Council.”<sup>76</sup> Thus the fact that Council’s decision was justified in part by the information from the advisor’s opinion was taken to mean that Council is constrained by that opinion. In other words, the Court held the Council to abide to the reasons made available in the public domain. The Council would not be able to justify different conclusions if it did not rely also on other scientific information (which in this case it did):

To the extent to which the Community institution opts to disregard the opinion, it must provide specific reasons for its findings by comparison with those made in the opinion and its statement of

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<sup>69</sup> Para 161.

<sup>70</sup> Para 154.

<sup>71</sup> Para 170.

<sup>72</sup> Para 171.

<sup>73</sup> Para 157, emphasis added. This claim was following from well established case law .

<sup>74</sup> Para 159.

<sup>75</sup> Para 268, emphasis added.

<sup>76</sup> Para 195.

reasons must explain why it is disregarding the latter. The statement of reasons must be of a scientific level at least commensurate with that of the opinion in question.”<sup>77</sup>

Yet in the same time the Court was at pains not to make Council’s decision pre-determined by SCAN’s opinion, because “the members of SCAN, although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities. Scientific legitimacy is not a sufficient basis for the exercise of public authority.”<sup>78</sup> What the Court was struggling to promote was to make the public authorities, laypersons as they are, make choices informed by the best scientific evidence yet not pre-determined by this evidence:

risk management ... can be properly performed by a public authority only if it acquires from the various bodies and departments working on its behalf ... sufficient technical knowledge to grasp the full significance of the scientific analysis performed by the independent experts and to decide, in full knowledge of the facts, whether a preventive measure should be taken and, if so, which.”

Taking into account the different principles which should guide epistemic and practical judgements discussed above, this should come as no surprise. The legitimate way to respond to uncertainty is to allow public authorities to draw different conclusions from the same evidence. This rationale explains the almost baroque holding that the Council may “rely on certain aspects of the scientific analysis.”<sup>79</sup> By allowing the political authorities to rely only *partly* on scientific opinions, the Court intended to encourage them<sup>80</sup> not to treat “The Science” as a black-box but to engage with the scientific arguments and if need be, to balance them differently with regard to the values they are called to protect. On other accounts this partial reliance would appear as allowing the authorities to cherry-pick the scientific advice. The only way for the Court to ensure that the new freedom to take different view on the same evidence will not violate the principle of non-arbitrariness was to engage itself in rigorous judicial review.

As for the review itself, the Court did not discuss much the intensity of review, nor its own role in imposing discipline of reason; it only reiterated the mantra that it is a case of discretion and it will review the decision only for manifest error, misuse of powers or excess. However the judgement itself was a striking departure from the lenient earlier jurisprudence of both the General Court and the ECJ. The review consisted of two parts. In the first the Court scrutinised whether Council had distorted SCAN’s findings, i.e. whether the same evidence could be assessed differently. In the second part, the Court reviewed whether from these factual assessment the Council could logically draw the conclusions it did (i.e. if he had made any ‘errors in conclusion’).

Thus, the Court satisfied itself that the institutions reasoning was sufficiently substantiated by with the available information, they did not distort the SCAN findings but only weighed the evidence differently, did not made manifest error in drawing conclusions on the basis of it, and narrowly upheld the contested regulation.

The rigorous scrutiny of the justification of the decision taken by the political authority in *Pfizer* may appear similar to that of the infamous *Lochner* case of the US Supreme Court.<sup>81</sup> *Lochner* is criticised as allowing the courts to second-guess the legislature on the substance of the adopted rules. There the Supreme Court reviewed a statute limiting the working hours of bakers on the ground of health concerns. The Supreme Court substantively re-evaluated the arguments for protection of public health and decided that the measure was “unreasonable, unnecessary and arbitrary interference” in

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<sup>77</sup> Para 199.

<sup>78</sup> Para 201.

<sup>79</sup> Para 200.

<sup>80</sup> According to many observers, Chalmers in particular, this effort backfired and made the community institutions surround themselves with the best available expertise only to defer to it.

<sup>81</sup> *Lochner vs. New York*, 198 US 45 (US Supreme Court).

contractual freedom. Even though the *Pfizer* court seems to do that as well, in my view it is quite different. What the Court was doing was rigorous evaluation of the quality of evidence, and also review of validity of conclusions. As the evidence was inconclusive, i.e. allowed more than one logical conclusion, the Court allowed the public authorities to make the ultimate choice. The judicial approach in *Pfizer* should rather be called legislative due care review and the more appropriate analogy is with the *Waterpenny* case of the German Constitutional Court.<sup>82</sup> There the court reviewed the constitutionality of legislative act which was justified with economic arguments. It required from the legislature, “when introducing social science evidence into their considerations ... to take due care in not glossing over the evidence and being circumspect in gathering enough of it. ... to engage in an extensive procedure of fact finding and hearings prior to legislating, just in order to make sure that the act under controversy will survive before the constitutional court.”<sup>83</sup> Similarly, *Pfizer* established a tight standard for due legislative care. It may be debatable whether the *Pfizer* Court was too lenient or too rigorous, yet it did open space for value judgements and political sensitivities which the *Lochner* court did not, and that is why it ruled for the administration in the end of the day.

It is debated whether this new test was stringent or lenient. On one side, Corkin claims that *Pfizer* put the “evidential bar so low that the community institutions should, in most cases, be able to make their regulations review-proof in spite of any “inconvenient” scientific advice.”<sup>84</sup> Others think the test was too stringent and placed unbearable evidential burden on the institutions (Chalmers) and impeded their ability to react to the unexpected (Fisher). According to Chalmers the Court allowed to the authorities to stray from SCAN’s opinion only because two conditions were fulfilled: “the Council relied upon other scientific evidence of equivalent probative value and gave reasons for why it departed from SCAN’s opinion.”<sup>85</sup>

If we distinguish the scope of discretion from the reasoning rigour that may be required in exercising it both sides are correct.<sup>86</sup> Institutions may have wide array of options for possible action yet be subjected to a stringent requirement to derive their choice from persuasive evidence. Even though *Pfizer* was apparently departure from earlier cases like *FEDESA* or *Angelopharm*<sup>87</sup> Corkin correctly notes that it “fit[s] comfortably into the same process-perfecting tradition.”<sup>88</sup> If Fisher was right to say that the Court limited the scope of discretion in applying the precautionary principle the ban would be overturned. On what she calls rationalist-instrumentalist approach the EU institutions would not be allowed to deviate from SCAN’s opinion. Chalmers is more to the point, because in his view the discretion was not limited, but only its exercise was made more difficult by the additional burden for justification. Indeed, even though the Court upheld the ban, the review was rigorous and if the judgement is juxtaposed to *FEDESA* it becomes obvious that this was not a limited review as Corkin believes. Yet is correct to note that *Pfizer* opened space for political judgement (in the face of the Communication). Yet again, with regard to the aftermath of the case, Chalmers and Fisher are rightly concerned that the Court placed so heavy justificatory burden to the institutions who wish to deviate from advisors, that they effectively never did it again.

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<sup>82</sup> *BVerfG Entscheidung, Gen. 413/88 and 1300/93* (BVerfG).

<sup>83</sup> Jürgen G Backhaus, ‘Harmonization of Law in the European Union’ in Peter K Newman (ed), *The New Palgrave Dictionary of Economics and the Law*, Macmillan Reference, Stockton Press (1998).

<sup>84</sup> Joseph Corkin, ‘Regulating Risk Regulation: How the Court of Justice ensures the European Community responds to both popular and scientific voices’ (SCARR: Social Contexts and Responses to Risk 2002), p. 20.

<sup>85</sup> Damian Chalmers, ‘Food for Thought’: Reconciling European Risks and Traditional Ways of Life’ (2003) 66 *Modern Law Review* 532-562, p. 541.

<sup>86</sup> Fisher apparently contrasts the breadth of discretion with the use of rigorous methodology, and this is why she is very critical of *Pfizer* and its progeny.

<sup>87</sup> See note 65.

<sup>88</sup> Corkin, ‘Regulating Risk Regulation: How the Court of Justice ensures the European Community responds to both popular and scientific voices’ (n 84), p. 15.

Alberto Alemanno suggested that peer-review should be practiced in risk assessments, where “it involves an in-depth assessment of the assumptions, calculations, alternative interpretations, methodology and conclusions. In particular, by taking the form of a deliberation, it involves an exchange of judgements about the appropriateness of methods and the strength of the author’s inferences.”<sup>89</sup> In my opinion the *Pfizer* court was very close to doing that. Its review, just like the peer reviews aimed to ascertain transparency and consistency of reasoning and inclusion of all relevant argumentation. To generalise beyond the particular case, both the peer editing an academic article and the reviewing court have to engage substantively with the argumentation, while abstaining from second guessing the assessments and the conclusions under review. Currently *Pfizer* is the leading authority on the precautionary principle in the EU. However, for the ten years since it was decided its rigour remains unmatched<sup>90</sup> so my claim for the potential of courts to exercise epistemic vigilance may be overblown. In the recent *Gowan* case,<sup>91</sup> the Commission had deviated from the received expert advice to restrict the use of certain substance for plant protection. On its surface the ECJ followed the earlier reasoning of the General Court in *Pfizer* and confirmed that the Commission could not adopt unjustified restrictions without scientific justification,<sup>92</sup> and claimed to have verified whether the facts it relied on were accurately stated and supported the conclusions reached. But it did so perfunctorily and failed to control the steps of the reasoning process which lead to the decision as was done in *Pfizer*; remarkably it failed to review whether the Commission could modify its own position without stating reasons or having new justification. In view of one commentator it reduced the reason giving requirement to a duty of production and not a duty of persuasion; it surrendered its role as gatekeeper of precautionary action thus undermining the legitimacy of the decision-making process in cases of uncertainty.<sup>93</sup> On the account suggested here, a more rigorous review leading to occasional strokes of arbitrary actions of the EU institutions would strengthen their legitimacy. Unfortunately, this time is yet to come.

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<sup>89</sup> Alberto Alemanno, ‘EU Risk Regulation and Science: The Role of Experts in Decision-making and Judicial Review’ in Ellen Vos (ed), *European Risk Governance - Its Science, Its Inclusiveness And Its Effectiveness*, vol. 6 (Connex Rep. CONNEX 2008), p. 66.

<sup>90</sup> In Fisher’s view “neither the court[s], nor the AGs engage in a particularly careful analysis of the scientific uncertainties involved” Fisher, ‘Risk regulation and administrative constitutionalism’ (n 36), p 238.

<sup>91</sup> Case C-79/09, *Gowan v. Ministero della Salute*, Judgment of 22 December 2010.

<sup>92</sup> Para 53.

<sup>93</sup> Case note, Alberto Alemanno, ‘Gowan (C-79/09)’ (2011) 48 *Common Market Law Review* 1329-1348, 14.

## Conclusion

The Commission of the European Union felt the need to increase its legitimacy by imposing some method for discipline of reason when applying the precautionary principle. For that purpose it adopted a Communication which turned what was thus far broad and empowering principle into a clear-cut formula or bright-line rule, which would function ideally with quantifiable scientific conclusions untainted with political considerations. It is arguable whether the nature of the regulated matter, marred by uncertainty even when the best available science is employed, could be subject to such framework at all. Without explicitly departing from this interpretation, in *Pfizer* the Court allowed for more flexible balancing of evidence with regard to the values at stake and made best efforts to put the EU institutions back in charge of doing that. It had clear intent both to keep political authorities responsible for the choices, and in the same time make their decisions informed by the scientific expertise. This was delicate task, as the line between mandating the institutions to defer to experts on life and death issues, and allowing them free sway to disregard science is thin. On the question whether and how much the authorities are constrained by the opinion of their expert advisors hangs the balance between scientific and political legitimacy of the Union regulation. Holding that SCAN's opinion is not binding would risk arbitrariness of decisions and stripping the independent risk assessment of any meaning. Holding that it is binding would shift all decision-making power to obscure expert bodies. By allowing the Union institutions to rely on the provided scientific advice but to draw different conclusions, the Court struck a middle ground. In the parlance adopted here, it enforced a modified version of Commission's own formula for discipline of reason and argument-sensitive decision-making.

The way the Court seemingly squared the circle was by rigorous review of the quality of information and of the validity of conclusions, and deferring to the outcome of the balancing. This was its attempt to ensure that in conditions of uncertainty the choice will be open to the Union institutions but that they will remain responsive to scientific argumentation albeit the balance will be conditioned by the values at stake.

Yet the rigour of Court's approach may have backfired. The burden to justify deviation from expert advice encouraged the Union institutions to defer to the received expertise rather than critically engage with it. *Pfizer* judgement was followed by proliferation of expert advisory agencies in the EU, which are likely to provide highest quality of expertise, thus promoting scientific legitimacy, however this very excellence of the available epistemic base makes all but impossible for the Commission to find alternative source of knowledge if it were to make an independent choice.

With regard to the account developed in the beginning of the paper, in *Pfizer* the General Court demonstrated that judiciary is able to evaluate how evidence was used or misused by political authorities. It also showed the ability of courts to hold the authorities up to their own standards for argumentation. Finally, if we can generalise the analysis of precautionary principle as a formal method for republican governance, it shows that formulas add rigor to decision-making, reduce its arbitrariness, make it sensitive to arguments, new evidence and changes of belief. Procedurally, this makes hidden assumptions and value judgements explicit, provides for transparency and allows quality control, by judges or critical public. The limits of the formula are also made obvious – formulas may bring about consistency and thus fairness, but cannot provide The One Right solution, the use of independent scientific expertise does not prevent political contestation, it only shifts it into different domain. That is why instead of searching for what is unattainable, the authorities and reviewing courts should rather gear the decisional framework to integrate competing evidence and diverging interests, thus merging scientific and political legitimacy rather than segregating them.



It is often suggested that guidances like the Communication and soft law in general structure discretion;<sup>94</sup> on the suggested account that is to say that they facilitate the argumentative rationality and make the decision making reasoned and non-arbitrary. The soft instruments are methods for discipline of reason, which ideally would constrain the decision-maker to act non-arbitrarily yet would not deny it the necessary flexibility of judgement and would not relieve it from the flexibility for that judgement. While the soft instruments themselves would often suffice as a method, I hope to have showed how courts can enforce (and reshape!) it.

Note that although the courts can control the rigour of reasoning of just about any authoritative decision, they rarely do. The oft-cited reason is lack of resources, but my guess is that courts willingness to take a hard look also depends on the availabilities of alternative reasons and narratives in the public sphere. Such is the argument of Alberto Alemanno who claims that impact assessments, which are increasingly used in US and EU, may become important source of reasons in the subsequent judicial review.<sup>95</sup> Similarly Wyatt suggests that the most important difference that the so called yellow card mechanism would make is that national parliaments would place in the public sphere new arguments which would facilitate rigorous judicial review.<sup>96</sup> The placement of reasons and arguments in the public sphere can enable judicial rigour, which in turn would increase the role of the reasons. This is a virtuous circle which is needed to implement the republican ideal of non-arbitrary governance.

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<sup>94</sup> For the classic argument see Joanne Scott and Susan P Sturm, 'Courts as Catalysts: Rethinking the Judicial Role in New Governance' (2007) 13 *Columbia Journal of European Law*.

<sup>95</sup> Alberto Alemanno, 'A Meeting of Minds on Impact Assessment: When ex ante Evaluation meets ex post Judicial Control' (2011) 17 *European Public Law* 1-20.

<sup>96</sup> Derrick Wyatt, 'Could a "yellow card" for national parliaments strengthen judicial as well as political policing of subsidiarity?' (2006) 2 *Croatian Yearbook of International Law and Policy* 1-17. He sees reason giving as important procedural guarantee for substantive correctness of the application of the subsidiarity principle and laments that currently the explanatory memoranda of legislative drafts have only brief and self-serving references to subsidiarity and the arguments against do not enter public domain at all. With the opinions of national parliaments this situation may change dramatically (but a chicken and egg problem, to take off them must see their opinions matter).

