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Anne Meuwese*

Two cases of Impact Assessment in environmental lawmaking and the role of evidence in the European legislative process¹

INTRODUCTION

“If we wait for perfect information, we will be in the situation of someone who doesn’t want to buy a PC unless the technology is flawless and will not be improved anymore. He will never end up buying it.”²

This statement by a European politician is about regulation. To be more precise, it is about REACH, the colossal piece of chemicals regulation that will feature later on in this chapter. The statement expresses a particular stance in the eternal dilemma of preparing regulation: how much information do we need before it is legitimate to initiate a regulatory solution? Especially in situations in which our knowledge is (still) limited and the potential risks are high, we need a general principle of procedure to govern our decision-making. The main principle that comes to mind is the precautionary principle, which has been put on the global map since the Rio ‘Earth Summit’ in 1992. Since then it has been made part of the European framework for decision-making and has been invoked by many stakeholders. However, the general impression is that “that the precautionary principle has had little effect on actual policy-making”.³ Since the last few years, EU policy makers have also put in place a more operational procedural device for managing information input into regulatory and legislative decision-making: impact assessment. This chapter zooms in on the way impact assessment can be and is being used in the European law-making process.

In 2002 the European Commission put in place an ambitious set of regulatory reform initiatives under the label ‘Better Regulation’ following recommendations from the Mandelkern group. The main initiatives were the following: a simplification programme, a screening exercise of all pending legislative proposals and in 2005 a dedicated programme to reduce administrative burdens triggered by EU policies by 25% by 2012. The most comprehensive initiative of all consisted of an integrated impact assessment (IA) system.⁴ The European Commission aimed to address the lack of ‘evidence-based decision-making’ in the EU legislative process by systematically carry out, in an early stage of the policy cycle, assessments of the potential economic, social and environmental effects of proposed regulatory interventions various societal groups. European impact assessment provides a template for assessing *ex ante* a range of regulatory activities, which comprises the following steps: problem identification, definition of the objectives, development of the main policy options, impact analysis, comparison of the options in the light of their impact and an outline for policy monitoring and evaluation.⁵ These analyses should be integrated with stakeholder consultation and therefore start early in the preparation process. An IA report⁶, in which the findings are summarised, is then published together with the proposal. This report is attached to the (legislative) proposal throughout the rest of the decision-making procedure, in which it meant to serve as “an aid to decision-making, not a substitute for political judgement”.⁷ Here impact assessment is supposed to thread the fine line between trumping democratic decision-making and correcting the evidence gap in EU lawmaking. In other

words, not only the quality of the scientific and economic evidence is important, but also the way in which it is used.⁸ The key question in relation to the EU impact assessment system is: does it facilitate a certain kind of use of evidence in lawmaking? First we will consider five ideal-typed ways of using impact assessment in the European legislative process. Then we will look at two case studies on environmental lawmaking with a core role for impact assessment, and consider to what extent they represent the ideal-types.⁹ The cases are the new Chemicals Regulation known as ‘REACH’ and the Thematic Strategy on Air Quality (CAFE). The former case sheds light on the role IA can play in dealing with contested scientific evidence in the European legislative process. The latter case involves a fairly uncontested scientific methodology, shifting the problem to the issue of how the data can be legitimately used to inform political processes.

USING IA IN THE EU LEGISLATIVE PROCESS: FIVE TYPES

In reaction to the integrated impact assessment procedure, people could be forgiven for shrugging their shoulders and stating ‘we have seen that before’. The EU has used many assessment devices over the years. And, how does impact assessment differ from or stand in relation to the precautionary principle? Does the choice to adopt regulatory impact assessment imply a marginalisation of the precautionary principle¹⁰, or rather a new way of putting this principle into practice as the policy documents of the European Commission suggest?¹¹

These questions are actually very useful in explaining the unique role of impact assessment in the European legislative process. Impact assessment and the precautionary principle have been presented as two rival ‘regulatory philosophies’.¹² However, the overlap between the two is greater than their differences. In the EU context, both devices are first and foremost attempts to objectify ‘common sense’ and are not meant to function as ‘decision generators’. The Communication on the Precautionary Principle emphasises that precautionary measures must be “based on an examination of the potential benefits and costs”.¹³ In both cases the methodological framework amounts to a light steer in the direction of cost-benefit analysis at most.¹⁴ In contrast with the common understanding of the subject, cost-benefit analysis (CBA) is only an (important) component of many types of IA; IA does not equal CBA. Whereas CBA is a method for decision-making; impact assessment is a highly structured process of policy formulation. However, American author Jonathan Wiener has concluded that “the Better Regulation initiative, especially the use of IA, is moderating the earlier fervor for the Precautionary Principle”.¹⁵ The meaning of the precautionary principle is also malleable in the sense that certain legislative proposals – for example REACH, see below – are clearly based on the precautionary principle in the eyes of some¹⁶, but do not amount to a truly precautionary approach in the perception of others.¹⁷

The interpretations regarding the correct use of IA in the policy process makes

of IA can also vary greatly. When the impact assessment procedure was established as a “general purpose impact analysis tool” it was based on the idea that competitiveness, sustainability and governance form a set of interlinked drivers of legislation, which must be brought out in the process.¹⁸ However, in the course of a few years, the emphasis shifted slightly towards more clearly delineated quantitative aims, such as administrative burden reduction. Otherwise the most important development has been the establishment of an internal quality control mechanism called the ‘Impact Assessment Board’ (IAB). The IAB scrutinises IA reports before they are published and coaches DGs in improving their level of analysis.

Yet the type of tests conducted and the information contained in the IA report determines only in part how evidence will influence the final decision. As we have seen, a crucial factor is how various actors treat the IA and – related to that – the status of the IA report in the legislative process. There are two agreements on this topic with the other Institutions: the Inter-Institutional Agreement on Better Lawmaking from 2003¹⁹ and the more informal ‘Common Approach to Impact Assessment’ from 2005.²⁰ At the same time this is the weak point of the system so far. It has proved difficult to come up with concrete shared norms, the other Institutions have a poor record in carrying out their own IAs and there are a lot of other actors involved, such as lobby groups and Member States, with whom no agreement has been concluded.²¹

This means that the concrete uses that the policy process makes of IA can vary widely. Even if there is a consensus that IA is a procedural device for infusing the lawmaking process with economic analysis but also with scientific evidence, there are still several ideal-typed modes of IA usage possible. According to the first type of IA use, the tool’s main function is seen as *‘speaking truth to power’*.²² This use assumes that the ‘true’ regulatory solution to a problem can be found in an impact assessment. If one holds that legislating is a part-legal, part-political activity, impact assessment could be viewed as merely explaining the various rationales and considerations behind the proposal. Using impact assessment for *‘reason-giving for legislative decisions’* does raise the question what role is left for the explanatory memorandum and also whether an update is not due after the final legislative decision. Third, in a more participatory conception of the lawmaking process, impact assessment would *‘provide a forum for stakeholder input’*. A variation to this, the fourth model, emerges when the emphasis is less on the value of public participation per se and more on the deliberative quality of the debate. In order for all arguments to be considered fairly (i.e. non-strategically), thick procedural rules that mitigate political impulses are needed. As part of such a web of rules, impact assessment could help to *‘structure the discourse’*. Fifthly and finally, there is a model which combines features of the types of use set out above: *‘highlighting trade-offs’*. Using impact assessment to clearly show the choices that political actors have and focussing on how they compare in terms of implications, comes fairly close to what is often called ‘warm cost-benefit analysis’ in the U.S.

IMPACT ASSESSMENT IN PRACTICE: ASSESSING ENVIRONMENTAL LAW AND POLICY

This final part of the chapter shows what kind of force IA can potentially be in European lawmaking by analysing two high-profile instances of EU environmental policy-making in recent years: the heavily contested chemicals regulation REACH and the clean air strategy CAFE.²³ These two policies share some important characteristics. Both are examples of ambitious environmental regulation and are associated with the large-scale costs and benefits typical for environmental policies. The main differences are that REACH is a targeted regulation, whereas CAFE represents a broad strategy. The latter case is in an area where a lot of scientific assessment has been done over many years; the former case is all about the problem of lack of scientific evidence.

REACH – WHEN THE STAKES ARE HIGH

The saga of the REACH impact assessment process is best summed up by the following statement: “I think impact assessments came of age with the REACH proposals on chemicals but, my word, it was a painful process”.²⁴ The expression ‘impact assessment process’ is used here on purpose, as many impact assessments were made. Throughout the legislative process for REACH (Registration, Evaluation and Authorisation of Chemicals) the estimation of costs and benefits played a major role.

A slightly longer, but still succinct way of summing up the REACH story goes as follows. The underlying reason why such a major overhaul of the European regulatory regime on the testing on health-related and environmental effects of all chemicals was possible was that almost everyone agreed that the old system was based on an injustice. Before REACH came along, ‘existing’ chemicals (on the market before 1981) were subject to a much lighter regime than the ‘new’ chemicals. This meant that there was a public health hazard related to the fundamental lack of information on chemicals introduced before 1981, but also that there was no level playing field for businesses involved due to the different sets of rules applied to chemicals depending on the time of their first introduction.²⁵ The bargain struck between stakeholder was for NGOs to accept some degree of deregulation of the sector overall (namely an increase the tonnage threshold for the information requirements)²⁶ and for industry to accept obligatory testing of ‘existing’ chemicals. REACH shifts the responsibility for the safety of chemicals to the chemicals industry, which must now register the 30,000 chemicals that are produced or imported at a quantity of 1 tonne or more per year with the newly established EU Chemicals Agency and provide information on the properties of the chemical. Furthermore, REACH calls for the progressive substitution of the most dangerous chemicals when suitable alternatives are known to exist.

When the ‘official’ Commission impact assessment of REACH was published in 2003,²⁷ as part of the pilot project for the then newly established impact assessment

system, the debate on reforming the EU regulatory system for chemicals had already been going on for five years.²⁸ Many partial assessments were already circulating at that stage. The chemicals industry, sometimes through the voices of the large Member States, France, Germany and the UK, had already made it clear that their costs arising from regulatory changes would be very high. There are reports that these concerns already influenced the original draft proposal, although it is unclear to what extent.²⁹

THE REACH IA DOCUMENT

The REACH IA contains seven objectives, possibly, as suggested by Pelkmans, too many to handle.³⁰ They are human health & environment, the competitiveness of the EU chemicals industry, prevention of fragmentation of the internal market, increased transparency of the regulatory regime, integration with international efforts, discouragement of animal testing and WTO conformity. REACH is made up of different instruments, each addressing a different set of objectives. This raises the question of whether there should not have been separate IAs for each part.

The REACH IA also illustrates an important dilemma in IAs as regards timing. Some fundamental choices regarding the set up of REACH were already made at the stage of the White Paper, but the assessments carried out at that stage were criticised for not providing sufficient detail for a comprehensive assessment. The 'official' Commission IA is the opposite. Because it was done at a late stage of the policy process it has a high degree of precision, but there is little scope for (fundamental) changes in the proposal. Subsidiarity was not analysed in details, since the proposed REACH regulation would be replacing a set of existing directives. But there was no such excuse for not analysing proportionality, which is undeniably an issue with the shift of the burden of proof on chemicals properties causing a lot of additional costs for industry. The analysis on this point is limited to a statement that "great care has been taken to ensure that the new legislation is not excessive in terms of scope, costs and administrative burden" by opting for a tiered approach for certain classes of chemical substances.³¹ A similar fate befell the consideration of 'lighter' interventions such as co-regulation or self-regulation, which were ruled out because "[c]hemicals is an area of Community activity that should be governed by full harmonisation because of the need to preserve the integrity of the internal market, to avoid trade distortions and conflicts and to guarantee a high level of protection of health and the environment."³² This is a circular argument that takes objectives – preserving the integrity of the internal market, avoiding trade distortions and guaranteeing a high level of protection of health and the environment – as the solution. This is a common pitfall in impact assessments, as it is more difficult to use the objectives as the benchmark for assessing impacts of various options, which would be the correct analytical approach.

For the purpose of this chapter I will not go into detail regarding the estimated cost. Suffice it to say that estimations varied hugely, although most major studies

arrived at a direct cost of a few billion euro. The pragmatic focus on cost-effectiveness fitted with the fact that real policy alternatives are no longer being considered, but it also led to accusations from different side that benefits were being ignored. The Commission had done a 'back of envelope' calculation concluding that the long-term health benefits of REACH could be in the region of €50 billion over 30 years (although the Commission pointed out that this was not intended as an estimate) and they could be as high as \$61 billion. On the environmental side, benefits were stated to be even more difficult to assess, but an example given of the many economic benefits was the potential to avoid future contamination of land.

USING THE INFORMATION FROM THE REACH IA

The high stakes behind the revision and the multitude of expected impacts caused a real flood of impact assessments, many of which only focused on one aspect of the proposal. Also the Commission did not stick to its own resolution of producing one, original impact assessment only as an objective document containing an integrated analysis covering all sensible policy options. Pressured by large stakeholders, such as CEFIC (European Chemicals Industry Council) and UNICE (European Industrial Federation) and after initial reluctance³³ the Commission agreed to undertake further impact assessment work, complementary to its extended impact assessment.³⁴ A Memorandum of Understanding (MoU) containing the commitment to "provide a framework for the efficient undertaking of further investigations on business impacts of REACH" was concluded on 3 March 2004 between four parties (CEFIC, UNICE, DG Environment and DG Enterprise). In order to lend the exercise greater legitimacy the 'REACH High Level Group on "Further Work on Impact Assessment"' was established, consisting of a broader group of stakeholders (industry, trade unions, environmental and consumer NGO's) and representatives from Council and Parliament.³⁵ On 14 July 2004 a contract for the new impact study was signed with KPMG. The aim was to collect evidence through case studies on how REACH affects businesses, especially with regard to the mass withdrawal of chemicals predicted by industry. A second new study was to be undertaken by the European Commission's 'Institute of Prospective Technological Studies' (IPTS) on the effects of REACH on Accession Countries/New Member States. The supervision of these two additional impact assessments, of which 'achieving a common understanding of the impacts' was the ambitious aim, was in the hands of the working group.³⁶ This is where the enterprise started to lose legitimacy in the eyes of the non-corporate stakeholders. The environmental lobby – represented in the working group by the WWF and the European Environmental Bureau (EEB) felt that a biased methodology was used which systematically excluded business benefits and exaggerated testing cost scenarios.³⁷ Further allegations included lack of access for the non-business members of the working group to 'key parts of the study'. After the publication of the KPMG impact study,³⁸ the debate over the numbers, the process and the methodology hardened even further.

According to the environmental lobby the impact assessment process did not succeed in mitigating ‘politics as usual’:

“Throughout the REACH debate, WWF and the other environmental NGOs have focussed on providing reasoned and reasonable input into the policy debate. We have been very disappointed that certain other parties to the debate, notably some representatives of industry, appear not to have taken this approach, and have been attempting to make political capital through scaremongering.”

Other stakeholders have considered the impact assessment process, and specifically the second, revised Commission impact assessment, as a game of give and take and called the actions of the environmental lobby ‘non-committal’ as in their view the environmental organisations opted out just because they did not like the results.

The controversial process *and* content were a fertile basis for further disagreement as the impact assessment went on to be used in the legislative process. The Dutch Presidency of the European Union also made an attempt to mediate between different appraisals of the impacts of REACH, by hosting a workshop on 25-27 October 2004. In the opinion of some this workshop was an example of an appropriate forum for business input, whereas others saw it as just a prologue to the negotiations in Council. At this event the approach that came to dominate the IA usage in this case, namely a pragmatic focus on cost-effectiveness at the expense of cost-benefit analysis of various options, was sealed.³⁹ According to the summary report there were already 36 impact assessments available at the time.⁴⁰ There would be more to come.

The assignment of the REACH dossier had led to a cat fight between the Industry Committee and the Environment Committee who had been handling REACH since the days of the White Paper, in consultation with the Industry and Legal Affairs Committees. The hard-fought solution was to let these three committees act as joint leads, with five other committees co-examining the REACH dossier. MEPs have expressed their despair at the unhelpfulness of the impact assessment process in the case of REACH, where they had to deal with almost as many impact assessments as position papers.⁴¹ Committee members from the Environment Committee, probably speaking about the *revised* impact assessment, voiced their concern that the impact assessment focussed on impacts on business and did not address impacts and benefits to the environment and on social issues. Commissioner Dimas pointed to the *original* IA when he said that “a comprehensive impact assessment had already been carried out, which showed that benefits strongly outweighed costs, pointing to the necessity for awareness-raising to be brought to the fore.”⁴² Vice-President Verheugen however broke ranks by criticizing the Commission proposal, stating that he saw REACH as “a clear example of legislation that is too complicated and too ambitious, too lacking in transparency”.⁴³

Although Parliament too seemed to view impact assessmen as a forum for partial views on the regulatory proposal it was by no means uncritical towards the role of stakeholders in the impact assessment process. For instance, an MEP of the Greens/European Free Alliance accused Cefic and ACC of continuing to use disproven figures: “Cefic and ACC went on to say that the cost of testing was estimated at €7 billion, although the estimate in the impact assessment from May 2002 said

that the cost would be between 1.4 and 7 billion, with a best estimate of 3.6 billion.”⁴⁴ Also, MEP Caroline Jackson (PPE), then chair of the Environment Committee, has floated the idea that if the industry wants to come up with an alternative proposal for REACH it should be accompanied by an impact assessment.⁴⁵

In accordance with the Inter-Institutional Agreement on Better Lawmaking, the impact assessment was also used in Council, although the way in which it was used is not necessarily in line with the spirit of that agreement. The REACH impact assessments are reported to have had influence on the outcome although by fuelling negotiations rather than more deliberative modes of decision-making.⁴⁶

To facilitate information provision to the Council negotiations, the Luxembourg Presidency followed the Dutch example and organised a REACH workshop on 10 and 11 May 2005. Oddly, this workshop focused on aspects which normally belong to the early stages of the IA process, namely data and options, whereas the Dutch workshop held in the previous year had focussed on cost-saving measures. Interviewed officials have asserted that the usefulness of this workshop as well as the previous one depended on the fact that they produced conclusions which could be fed straight into the negotiation process in Council. A press release from the Luxembourg Presidency reported that the “Council is committed to taking into account all the results drawn from the impact studies once the political decision is made”. Chairman Jeannot Krecké expressed the general stance on correct impact assessment use among members of the Competitiveness Council as follows “the purpose of impact studies is not to produce a perfect state of information on REACH, but rather to provide as much information as possible.” However, interviewees have indicated that there was a point past which IAs no longer played a role.⁴⁷

In all these debates and assessments the precautionary principle was conspicuously absent. It was present in the early REACH proposal – the one dating from the White Paper days –, but it is clear that by the time the legislative game began and the main concern was to get business on board, the focus shifted to the direct costs, a concern that is only very indirectly of interest to the precautionary principle.

THEMATIC STRATEGY ON AIR QUALITY (CAFE) – DEBATING COSTS AND BENEFITS

Unlike the REACH IA process, which has gotten mixed reviews at best, the IA process for the Air Quality Thematic Strategy (CAFE)⁴⁸ is generally seen as a success story, albeit a ‘compromised’ one.⁴⁹ By ‘compromised success’ the authors in question mean that both the environmental lobby and the industry lobby achieved *some* of their goals: the final outcome included tougher standards on emissions but not as strict as initially proposed. What is seen as only a partial success from the lobbyist perspective could indeed be a real victory for the usage of impact assessment, as it could mean that a balance was found between politics and ratio.

The joint impact assessment⁵⁰ of the Communication on Thematic Strategy on Air Pollution⁵¹ and the Directive on “Ambient Air Quality and Cleaner Air for Europe”⁵² has become known as the ‘CAFE impact assessment’.⁵³ The CAFE IA has

been hailed as one of the most comprehensive IAs ever produced by the Commission.⁵⁴ This was made possible by the existence of a wide array of studies on the topic. In this case, assessing the impacts was very much part of the policy preparation as a whole. The work was carried out in a Steering Group alongside several smaller working groups, allowing for involvement from various stakeholders (industry federations, environmental NGOs, research institutes and representatives from Member States). Not just the data but also the wider terms of reference (models, scenarios and assumptions) were discussed in this Steering Group and the working groups, which to some observers was a sign of inclusiveness of the IA process.⁵⁵

THE CAFE IA DOCUMENT

Some readers of the lengthy CAFE IA are left with the impression that some elements that were too lengthy to be fitted into the actual strategy document have been included in the IA report instead.⁵⁶ The objective mentioned in the IA is the following: “achieving levels of air quality that do not give rise to significant negative impacts on and risks to human health and the environment”. This is a fairly off way of formulating an objective, as the phrase includes a judgment (‘significant’), making it difficult to ascertain whether the objective has been achieved. As mentioned the IA made use of extensive studies that included advanced modelling developed over many years⁵⁷, causing most actors to be satisfied with the content of the IA.⁵⁸

USING THE INFORMATION FROM THE CAFE IA

This lack of controversy surrounding the content as such had implications for the *use* of the impact assessment too. For example, one observer who felt that DG Environment wrote up the IA in a biased way immediately added to that ‘it did not matter, since the numbers were there’. Thus, a good IA seems to be able to trigger a more rational political debate. However, that was not the whole story. During the legislative debates the most problematic element of the CAFE IA turned out to be the decision criterion, or rather, the alleged lack of it.

The IA report showed that although in all scenarios considered the benefits were greater than the costs, the cost curve rose sharply from a certain ambition level onwards with the benefits only increasing marginally. The policy option proposed by the European Commission was expected to deliver €42 billion in benefits per year at a cost of around €7.1 billion per year. The expected benefits included the prevention of 62,000 premature deaths. However, an earlier more ambitious proposal, reflected in an ‘option’ in the IA report, would have prevented 74,000 premature deaths, with the benefits still outweighing the costs by a significant factor.

In the words of an environmental think tank: “[T]he Commission opted for an approach that reaped only the relatively low hanging fruits, although the Impact Assessment could have justified a more ambitious approach, as preferred by a majority of experts in the Working Group.”⁵⁹

This caused the European Parliament to ask why this more ambitious option had not been proposed by the Commission.⁶⁰ Some went even further and wondered whether this was a legitimate use of numbers in an IA and whether the Commission was not under an obligation to put forward the more beneficial option.⁶¹ Phrased differently, the Parliament implied that cost-benefit analysis should have been used as a decision criterion here, whereas the Commission implicitly took more of a cost-effectiveness approach. In doing so, the Commission lived up to its own motto that IA should be “an aid to decision-making, not a substitute for political judgement”.⁶²

But what that can mean in practice was neatly illustrated by the role the CAFE IA played in internal decision-making within the College of Commissioners of the European Commission, before the dossier got to the Parliament. The Thematic Strategy arrived to the decision table at a difficult time. The Better Regulation strategy was just being reformed to fit more closely the Lisbon agenda with its focus on competitiveness.⁶³ The package of seven environmental strategies, inherited from the Prodi Commission, was not received warmly by the new Commission and in particular by the Commissioner for Enterprise, Vice-President Verheugen. The College negotiated versions of the Strategies that could be passed as ‘Better Regulation proof’.⁶⁴ The CAFE IA was instrumental to this in the following way. Verheugen had asked Commissioner Dimas for Environment to come along and present the IA in front of the Competitiveness Council Group of Commissioners in early June 2005. In the view of DG Environment the IA supported the more ambitious option. But DG Enterprise and Verheugen thought the cost-aspect brought to light by the IA should be the decisive factor: the marginal benefits of the higher ambition level were low and therefore could not justify the costs to business. So discussion of the IA by the Commissioners, did not pre-empt the impression that the proposal only contained the less ambitious option because that was the one which had political support. However, the difference the IA process made in this case was that now the fact that the Commission chose a ‘B’ option was out in the open because it was obvious from the IA report.

The IA process managed fairly well to bring out the various trade-offs associated with the policy options. Although this process can be applauded as an instance of an IA actually aiding political decision-making, it also revealed how difficult it is to have a political discussion that does justice to the IA. This leads to diverging assessments of the appropriateness of the use of IA in this case: to some ‘it was an epiphany seeing an IA used as it should be’, to others the good quality of the IA was simply not reflected in the proposal.

CONCLUDING REMARKS

What to take away from the case studies? A brief warning is warranted here: the stories of the REACH and CAFE impact assessments are about what *can* happen with impact assessment, but due to the exceptional circumstances of the cases and the early stage of the EU IA system, they should not be taken as *the* account of impact assessment in EU lawmaking. Interestingly both cases presented here have been used as examples of both good and bad practice in the literature. This can be explained by the wide-spread disagreement on what is meant to be, and what should be, the correct use of IA by political actors.

It should also be noted that the factual circumstances differed enormously from the one case to the other. The REACH debate relied on many scattered IAs on the subject; in the case of CAFE there was one lengthy comprehensive assessment. In the case of REACH the IA process, the IA content and the use of IA in the legislative process were contested. The Thematic Strategy on Air Quality (CAFE) shows a different picture: although there was little contestation regarding the process and the content, the use of impact assessment was still controversial. It is possible that with REACH the process and the content were so contested that stakeholders did not get around to arguing about the use, especially because there were too many partial IA's with unclear authority. For CAFE the mechanism was reversed: a relatively uncontested process and a content relying on years of research paved the way for controversy around the use.

Looking at the case studies through the lense of the ideal-typed modes of use of IA, the REACH case study shows that many actors – implicitly or explicitly – embraced a ‘providing a forum for stakeholders’ use. There are positive aspects to this usage. By integrating economic and scientific analysis with the stakeholder consultation, some big stakeholders got on board because the extreme numbers regarding the cost could be refuted and because a substantial cost reduction could be shown.⁶⁵ However, for other stakeholders the inequality in terms of resources available to produce additional studies to industrial lobby groups on the one hand and environmental NGOs on the other, delegitimised the process.⁶⁶ Also, the REACH case shows that there is a risk that short- term and cost-based arguments are prioritised to some extent.

The CAFE case, however, shows that long terms benefits can play a decisive role too, offering a glimpse of using IA to ‘highlight trade-offs’ might work. Process and content went relatively uncontested here, but the use of the IA in the decision-making process, revealed disagreement on the appropriate decision criterion, and in particular on the role of CBA. The CAFE case does show that more transparency triggers a need for even more transparency. At least part of the controversy could have been avoided if the decision criterion applied by the College of Commissioners would have been made explicit in the report .

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Note

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¹ This chapter is a shortened and updated version of the paper delivered at the Young Researchers Workshop on Science and Law, 'Scientific Evidence in International and European Law', 31 May - 1 June 2007, Lecce

² Luxembourg Presidency, Press Release, Jeannot Krecké on REACH: "I think that with 50 impact studies, the time has come for the Council to conclude", 6 June 2005, <http://www.eu2005.lu/en/actualites/communiqués/2005/06/06reach/index.html> (last accessed on 15 May 2007).

³ Eckley, N. & Selin, H. (2004). All talk, little action: precaution and European chemicals regulation. *Journal of European Public Policy*, 11:1, 78-105.

⁴ Not to be confused with the Community law obligation for Member States to carry out 'environmental impact assessments' on projects or plans. See Council Directive 97/11 amending Directive 85/337 on the assessment of the effects of certain public and private projects on the environment, and Directive 2001/42 of the European Parliament and of the Council on the Assessment of the Effects of Certain Plans and Programmes on the Environment.

⁵ European Commission, Impact Assessment Guidelines, SEC(2005) 791. 15 June 2006 with an update on 15 March 2006.

⁶ Often simply referred to as the 'impact assessment' even if in fact the term 'impact assessment' covers the whole process and not just the report.

⁷ European Commission (2002). "Communication on Impact Assessment", Luxembourg, Office for Official Publications of the European Communities.

⁸ Boswell, C. (2008). The Political Functions of Expert Knowledge: Knowledge and Legitimation in European Union Immigration Policy. *Journal of European Public Policy*, 15:4, 471-488.

⁹ The case studies were carried out for my PhD thesis, defended at Leiden University on 8 February 2008.

¹⁰ Löfstedt, R. (2006). "The Plateau-ing of the European Better Regulation Agenda: An Analysis of Activities Carried Out by the Barroso Commission", *AEI-Brookings Joint Center for Regulatory Studies*. Washington.

¹¹ See for instance the European Commission Impact Assessment Guidelines, SEC(2005) 791.

¹² Löfstedt, R. E. (2004). The Swing of the Regulatory Pendulum in Europe : From Precautionary Principle to (Regulatory) Impact Analysis. *Journal of Risk and Uncertainty*, 28:3, 237-260.

¹³ European Commission (2000). "Communication from the Commission on the precautionary principle", Brussels. Wiener views this as a redefinition of the precautionary principle by the

Commission and seems to see a link with the introduction of IA, but it should be noted that the 2000 Communication predates the Action Plan on Better Regulation. Wiener, J. B. (2006a). Better Regulation in Europe. *Current Legal Problems*, 59 447-518.

¹⁴ It is also in line with the Court of First Instance's decision in the Pfizer case (Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305) which stipulated that some economic assessments is required, the Institutions still have a rather large degree of discretion in carrying out these assessments. See also De Sadeleer, N. (2006). The Precautionary Principle in EC Health and Environmental Law. *European Law Journal*, 12:2, 139-172.

¹⁵ Wiener, J. B. (2006b). "Better Regulation in Europe", *Duke Law School Legal Studies Research Paper Series*.

¹⁶ Transatlantic Consumer Dialogue, <http://www.tacd.org/docs/?id=253>.

¹⁷ Hey, C., Jacob, K. & Volkery, A. (2006). "Better regulation by new governance hybrids? Governance models and the reform of European chemicals policy", *Environmental Policy Research Centre Berlin*.

¹⁸ Radaelli, Claudio C. M. & Meuwese, A. C. M. (2009). "Better Regulation in the European Union. The political economy of impact assessment", in Jacob, K. & Hertin, J. (eds.) *Evaluating Integrated Impact Assessments (EVIA) Handbook*. Springer.

¹⁹ European Commission, European Parliament & Council of Ministers (2003). "Inter-Institutional Agreement on Better Lawmaking", Brussels.

²⁰ European Commission, European Parliament & Council of Ministers (2005). "Inter-Institutional Common Approach to Impact Assessment", Brussels.

²¹ Meuwese, A. C. M. (2007). "Inter-institutionalising EU Impact Assessment", in Weatherill, S. (ed.) *Better Regulation*. Oxford, Hart Publishing.

²² The famous expression is from Aaron Wildavsky, who used it in a slightly ironic way however.

²³ These case studies were carried out for my PhD thesis 'Impact Assessment in EU Lawmaking', defended at Leiden University on 8 February 2009. The manuscript was published as Meuwese, A. C. M. (2008). *Impact Assessment in EU Lawmaking*, The Hague, Kluwer Law International. A more detailed description of the two case studies, as well as a justification of the methodology used can be found there.

²⁴ John Cridland, Confederation of British Industry (CBI), see House of Lords (2005). "Ensuring Effective Regulation in the EU. Report with Evidence", in European Union Committee (ed.) *9th Report of Session 2005-06*.

²⁵ Applegate, J. S. (2006). "The Government Role in Scientific Research: Who Should Bridge the Data Gap in Chemical Regulation?" in Wagner, W. E. & Steinzor, R. (eds.) *Rescuing Science from Politics. Regulation and the Distortion of Scientific Research*. Cambridge, Cambridge University Press.

²⁶ This analysis of the situation is inspired by the remarks of a senior campaigner of environmental NGO Friends of the Earth giving evidence before the Environmental Audit Committee of the House of Commons in the context of a report on the functioning of impact assessment.

²⁷ The official REACH proposal was published by the European Commission with an 'extended impact assessment', as it was then still called, on 29 October 2003, so after five years of debate. See European Commission (2003b). "Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) (on Persistent Organic Pollutants). Proposal for a Directive Regulation of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals", Brussels. For the IA see SEC(2003) 1171. Exceptionally, the IA was a co-prepared by DG Environment and DG Enterprise.

²⁸ One could take April 1998 as the starting point of the policy debate, when the Informal Environment Council expressed concerns about the chemical regulatory system. In November of the same year the European Commission published a report on the functioning of the four main chemicals regulatory instruments. See also European Commission (1998). "Report on the func-

tioning of the four main current chemicals regulatory instruments", Brussels.

²⁹ EEAC European Environment and Sustainable Development Advisory Councils (EEAC) (2006). "Impact Assessment of European Commission Policies: Achievements and Prospects", Brussels, EEAC Working Group Governance.

³⁰ Jacques Pelkmans during a presentation on the REACH IA at the CEPS conference "Impact Assessment in the EU, taking stock and looking forwards" on 23 January 2006 in Brussels.

³¹ European Commission (2003a). "Extended Impact Assessment on Framework Legislation on Chemical Substances (establishing REACH)", *Commission staff working paper*. Brussels.

³² Ibid.

³³ Mr John Cridland, Deputy Director-General, Confederation of British Industry (CBI), see House of Lords (2005). "Ensuring Effective Regulation in the EU. Report with Evidence", in European Union Committee (ed.) *9th Report of Session 2005-06*. London, The Stationery Office Limited. See also Schörling, I. (2004). "REACH - The Only Planet Guide to the Secrets of Chemicals Policy in the EU. What Happened and Why?" in Greens/European Free Alliance (ed.) Brussels.

³⁴ http://ec.europa.eu/environment/chemicals/background/impact_assessment_intro.htm.

³⁵ European Environmental Bureau & WWF DetoX Campaign (2005). "REACH impact assessments. Assessing EU Environmental Policy Impacts. A Critical Evaluation of Impact Assessments carried out for Europe's chemical policy reform (REACH)".

³⁶ Ibid.

³⁷ EEB and WWF Briefing, 'REACH Impact Assessment: Business will not lose essential and safe chemicals', 27 April 2005.

³⁸ The Working Group held its final meeting on 13 April 2005 where the findings were presented and discussed.

³⁹ Netherlands Presidency of the Council of the European Union (2004). "Conclusions and recommendations of Workshop on REACH Impact Assessments", The Hague.

⁴⁰ ECORYS & OpdenKamp Adviesgroep (2004). "The impact of REACH. Overview of 36 studies on the impact of the new EU chemicals policy (REACH) on society and business. Workshop REACH Impact Assessment, 25th - 27th October 2004, The Hague, The Netherlands".

⁴¹ European Voice (2005). "Time to take a scalpel to the EU's regulatory fat?(Arlene McCarthy vs Monica Frassoni)", Brussels.

⁴² At the European Parliament Seminar on "The new REACH legislation", jointly organised by the Committee on the Environment, Public Health and Food Safety, the Committee on Industry, Research and Energy and the Committee on Internal Market and Consumer Protection on 19 January 2005.

⁴³ European Parliament press release, The Internal Market: mission still unaccomplished, http://www.europarl.eu.int/news/expert/infopress_page/054-253-257-9-37-909-20050912IPR00218-14-09-2005-2005—false/default_nl.htm.

⁴⁴ Waxman (2004). "A special interest case study: The Chemical Industry, the Bush Administration, and European Efforts to Regulate Chemicals", in US House of Representatives Committee on Government Reform - Minority Staff Special Investigations Division (ed.) Washington, USA.

⁴⁵ The AllChemE Seminars, Where science meets society. The socio-economic importance of chemistry in Europe. <http://www.allchemeseminars.org/downloads/04-01-28/Final%20Report%20%2028-01-04.pdf>.

⁴⁶ Better Regulation, Progress report from the Presidency 5 October 2005, p. 3. See also statement by Mr Hutton, House of Lords (2005). "Ensuring Effective Regulation in the EU. Report with Evidence", in European Union Committee (ed.) *9th Report of Session 2005-06*. London, The Stationery Office Limited.

⁴⁷ Informal interview Council official.

⁴⁸ European Commission, Impact Assessment of the Communication on Thematic Strategy on Air Pollution and the Directive on "Ambient Air Quality and Cleaner Air for Europe", Commission staff working paper, SEC (2005) 1133.

⁴⁹ Mahoney, C. (2007). Lobbying Success in the United States and the European Union. *Journal*

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⁵¹ European Commission (2005c). "Thematic Strategy on Air Pollution", *Communication from the Commission to the Council and the European Parliament* Brussels.

⁵² European Commission (2005b). "Proposal for a Directive on "Ambient Air Quality and Cleaner Air for Europe"", *Communication from the Commission to the Council and the European Parliament* Brussels. The proposed directive incorporates the First, Second and Third Daughter Directives on Clean Air, as well as the Exchange of Information Decision.

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⁵⁴ Löfstedt, R. (2006). "The Plateau-ing of the European Better Regulation Agenda: An Analysis of Activities Carried Out by the Barroso Commission", *AEI-Brookings Joint Center for Regulatory Studies*. Washington. "A major effort in 'Better Regulation' in the environment field will be reflected in the seven Thematic Strategies".

⁵⁵ European Environment and Sustainable Development Advisory Councils (EEAC) (2006). "Impact Assessment of European Commission Policies: Achievements and Prospects", Brussels, EEAC Working Group Governance.

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⁵⁷ Wilkinson, D., Monkhouse, C., Herodes, M. & Farmer, A. (2005). "For Better or for Worse? The EU's 'Better Regulation' Agenda and the Environment", London, Institute for European Environmental Policy (IEEP),.

⁵⁸ The European Parliament rapporteur, Dorette Corbey also indicated in a phone interview that she found the data in the IA report convincing.

⁵⁹ Wilkinson, D., Monkhouse, C., Herodes, M. & Farmer, A. (2005). "For Better or for Worse? The EU's 'Better Regulation' Agenda and the Environment", London, Institute for European Environmental Policy (IEEP),.

⁶⁰ Phone interview with Dorette Corbey. Rapporteur Corbey asked the Commission for clarification on the reason behind the choice for ambition level a+ but did not get an explicit answer. Although the CAFE dossier does not fall within the ambit of the co-decision procedure and all the European Parliament and the Council can do is issue an opinion, the Strategy was discussed thoroughly.

⁶¹ European Environment and Sustainable Development Advisory Councils (EEAC) (2006). "Impact Assessment of European Commission Policies: Achievements and Prospects", Brussels, EEAC Working Group Governance.

⁶² European Commission (2002). "Communication on Impact Assessment", Luxembourg, Office for Official Publications of the European Communities.

⁶³ Radaelli, C. M. (2007). Whither Better Regulation for the Lisbon Agenda? *Journal of European Public Policy*, 14:2, 190-207.

⁶⁴ According to Lofstedt a special hearing was held for this purpose. European Environment and Sustainable Development Advisory Councils (EEAC) (2006). "Impact Assessment of European Commission Policies: Achievements and Prospects", Brussels, EEAC Working Group Governance.

⁶⁵ Jacobs and Associates, 'The Better Regulator', Spring/Summer 2005, p. 2.

⁶⁶ Schörling, I. (2004). "REACH - The Only Planet Guide to the Secrets of Chemicals Policy in the EU. What Happened and Why?" in Greens/European Free Alliance (ed.) Brussels. Wilkinson, D. & Monkhouse, C. e. a. (2005). "For Better or for Worse? The EU's 'Better Regulation' Agenda and the Environment", London, Institute for European Environmental Policy.