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**Quality assurance in impact assessment systems: the
role of oversight bodies in the US and in the EU**

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Anno Accademico 2011/2012

Abstract

With the increasing need of both quantitative and qualitative improvement of the regulatory activity across the world, many governments have instituted or have proposed the institution of Regulatory Oversight Bodies (ROBs). The purpose of these bodies is primarily the review of legislative initiatives, with the goal being the improvement of the quality and efficiency of the regulatory system. When abandoning the academic notions of perfect and efficient markets, and taking conscience of the widespread market failures and inefficiencies that now characterize the economy, the importance of the key role that ROBs have to play in a country's life becomes blatant. Subordinating a country's regulatory activity to the check of technical parameters is most certainly the main road leading to a fast implementation of a regulatory review process, nonetheless, such an important mechanism of the legislative life of a country would not stand straight if not with the addition of a second support: the political oversight. This in turn leads to the accountability of the regulatory bureaucratic machine to elected officials, legitimizing it and in turn empowering the key nodes of it. The focus will be posed upon the US regulatory oversight body: the OIRA (The Office of Information and Regulatory Affairs), and on the EU regulatory oversight body: the IAB (the Impact Assessment Board), being these two the most active laboratories in the field.

Table of contents

Preface: The increasing need for bureaucratic watchdogs: the role of Regulatory Oversight Bodies and the environment in which they operate

- I. The Office of Information and Regulatory Affairs
 - I.1. Introduction to the OIRA: Purposes and responsibilities
 - I.2. Role of politics: the Presidential control model
 - I.3. Role of politics: White House involvement in the regulatory activity
 - I.4. Conclusions

- II. The debate on Cost-Benefit Analysis: Pros and Cons

- III. The Impact Assessment Board
 - III.1. Introduction to the IAB
 - III.2. Quality of EU impact assessments
 - III.3. Role of politics: accountability
 - III.4. Conclusions

- IV. Conclusion

- V. Bibliography

Preface:

The increasing need for bureaucratic watchdogs: the role of Regulatory Oversight

Bodies and the environment in which they operate

Regulatory oversight bodies (ROBs) constitute a rather peculiar class of legislative bodies; they have been given the mandate to control the rule-maker, that is: he who has demanded the institution of it. Stating it in these terms makes these bodies undoubtedly seem rather revolutionary and innovative, and in fact the mainstream scholar doctrine studying the role and tasks of the ROBs delivers this message: ROBs are those legislative organs having the common aim of maximizing the efficiency of the regulatory processes through the use of the tools of transparency, accountability and evidence-based analysis (OECD, 2011). Who could possibly blame the institution of them? The aim of the analysis hereafter illustrated is testing up to which point the praises of the mainstream doctrine regarding the ROBs are to be blindly cited when referring to these. The effectiveness of ROBs in ensuring the correct implementation of measures favouring the efficiency of the regulatory processes is too much subordinated to a variety of components to judge them taking them altogether. Every single ROB may in fact be potentially largely different from that in place even in the neighbouring country, as the range of action granted to the body, the degree of empowerment, and the environment surrounding them typically do change from country to country.

All around the globe each ROB has a distinctive institutional placement, which in turn determines its authority within the bureaucratic hierarchy and the degree of empowerment granted to the office. The typical ROB is posed under the executive control of the government, although it may as well be located in the judicial or legislative branch. The empowerment, meaning the scope of its reviewing authority, varies as well: from the reviewing of binding and non-binding legislative proposals, as in the case of the IAB, to the reviewing of the regulations only, as in the OIRA case. The environment in which ROB's have to execute their task constitutes as well an important variable, as it may be an environment characterized by political conflicts or not, rather than one featuring a high number of relationships or not. Only when analyzing these dimensions altogether, making a statement on the ROB's effectiveness is worth, as the variables of the "efficacy-equation" may in fact deliver both positive and negative results.

The principal recipient of the work carried out by the ROB's is the population at large, and if viewing the issue with a tip of romanticism, one could state that the aim of these bodies is ultimately that of maximizing the "citizen-surplus". For this reason the institution of a ROB in every regulatory system is to be praised, and for this reason each ROB must be analyzed thoroughly.

I. The Office of Information and Regulatory Affairs

I.1. Introduction to the OIRA: purposes and responsibilities

The influence of politics on regulatory activity has been a prolific source of scholar debate in the last 30 years; that is from the promulgation of the Paperwork Reduction Act (1980), which created the OIRA posing it within the Office for Management and Budget (OMB), located in the Executive Office of the President. The following milestone is constituted by the Executive Order No.12291 (order giving OIRA the authority to review proposed regulations and requiring a cost-benefit analysis on some regulations) promulgated by President Reagan's administration (1981), with its aim being that of specifying that the OIRA was to operate under the direct control of the President; thus under an executive control regime. The first attempts of increasing the accountability of the regulatory process may be traced back to the administration of President Nixon, but it was the issuance of EO No.12291 that formally addressed the need for accountability. Since then, the duties and responsibilities of OIRA have been further defined. Every President since Reagan has attempted to increase the agencies' decision-making accountability by requiring that the OMB review all major regulations (Cecot, C., *et al.* 2008). The first task appointed to OIRA stems directly from the Executive Order No.12291, requiring the performance of an impact assessment analysis on proposed regulations. This first task aims at subordinating the regulatory activity to an analytically identifiable criterion, in order to provide an empiric evaluation of the regulation so to

deliver assistance for executive or legislative decision-making. The second duty assigned to the OIRA is that of controlling the agencies' activities on behalf of the President, that is: the exertion of executive oversight on the regulatory activity. This stems directly from the Executive Order No.12866, promulgated by President Clinton's administration that endorsed and defined presidential oversight on regulatory activities. The EO No.12866 provides more accountability to the system, and requires the agencies to perform a RIA on those regulations that have an estimated impact superior to \$100 million. This benchmark does not imply that all proposals having an effect inferior to \$100 million do not deserve major attention and work by the institutions, but instead it is directed at increasing the efficiency of the regulatory review process through a diminishment of the workload requested to the agencies, and consequentially of the impact assessments that have to be reviewed by the OIRA. As it will be explained in section 3, the use of benchmarks in the decision of which regulatory proposals have to be accompanied by an impact assessments is a common feature of all the main regulatory systems, thus also of the IAB, although the criteria adopted might not be a strictly numerical one. The use of benchmarks is ultimately directed at protecting the quality of the impact assessments regarding "big" regulatory proposals, and not at ignoring the importance of "smaller" ones. It is when taking into consideration that the OIRA has a limited workforce and that time constraints are an important factor in the regulatory processes that the use of benchmarking policies reveals their pragmatic nature. Thus, the advantages of an empiric benchmark, such as the one used in the US, are mainly the fostering of the transparency of this aspect of the regulatory process and the provision of a reasonable resource allocation pattern to be followed.

Another characteristic of the US regulatory review process that distinguishes this system from others is the centrality assigned to the cost-benefit analysis (CBA). The advantages and disadvantages stemming from the use of this tool will be further discussed in section 2, but it is worth pointing out that the use of CBA in the US regulatory review process is so heavy, other than central, that the US has been called a cost-benefit state.

At a first glance, it may seem that OIRA has to carry on two contradictory co-existing roles that may not find an efficient application. That is because on one side OIRA has to perform an advisory task, and on the other it has to enforce the presidential will. Executive Order No. 12866 provides bureaucratic accountability to the overall regulatory activity, posing it under the eyes of the President, hence (at least theoretically) under the lens of the electorate and of the public opinion. This consequently relieves up to a certain extent the technocratic task of OIRA, subordinating its activity to the democratic parameters. The question to pose clearly arises from an analysis of the tasks that have to be undertaken by the OIRA: how much does the agency's technocratic aim affect the regulatory activity vis-à-vis the executive control (and the subsequent political constraint) it has to perform? What is the specific weight of the agency's technocratic aim in respect to the control it has to exert on behalf of the President of the United States? Furthermore: does the weight of one task overpower the weight of the other, and does the prevalence of one aspect of OIRA's activity change its originally intended nature making it a political organ itself?

While there may be no clear generic answer to these questions, there is the possibility to analyze whether these hypothetical outcomes are likely or not to come to reality. Certainly, even the most tenacious detractors of the activity exerted by the OIRA do not blame it of continuous failures, but rather of occasional ones. In fact, the failure frequency rate of regulatory processes, if resting within the definition of occasional and not leaking into the area of “rule”, is not even a relevant aspect of the matter for the purposes of the debate. The point being that if there is space for two or three mistakes, being them caused by will or by error, potentially there is space for thousands of them. The first way to counter this eventuality or, to be realistic, this current state of things, is analyzing the relational and legislative environment of the OIRA, so to identify the potential sources giving birth to potential biases.

1.2. Role of politics: The Presidential control model

Executive control over OIRA has been both praised and criticized. The debate has focused on the nature of the principles that could guide decision-making in exerting the oversight role. The spectrum of the sources of presidential will is characterized by two opposite views on the President’s activity. The first sees the President as the true representative of the People of the United States, carrying on their interests and will. This view seems to assert that the President is ultimately

lobby-proof, and that he is more likely than not to deliver balanced decision-making to the regulatory activity, maintaining national interests above factional interests.

Elena Kagan, in a 2001 *Harvard Law Review* article, argues that the presidency is the only institution that can provide accountability and efficiency to the regulatory activity, and that only the executive power, prerogative of the President, can assure the quick and efficient implementation of these. Other scholars in favour of presidential control state that executive control is the only way to provide a clear direction and effective policy coordination to the regulatory regime (Shapiro, S., 2006). This has been clearly one of the major factors that have contributed to the assignment of control over the OIRA to the White House. Scholars praising this kind of control seem to ignore the fact that when one speaks about the President one refers to a group of people, rather than to one person. Stating that the presidency is not constituted by one brain is no long shot, but it definitely would be stating that all the decisions made by the President's office come directly from the President himself. The President is the elected head of government and of the regulatory bureaucratic machine, his charge thus provides accountability for the actions of these, and requires him to apply a "moral rule" to these legislative organisms. The "moral rule" that the president is bound to apply, other than serve, stems directly from his tie to the constitution, and from the will of the people who he ultimately represents (will that could include possible moral restraints, such as religious ones, or indications on policy decisions, such as taxation ones). History provides some examples of the consequences that arise when there is the perception of a breach in the President's application of this contract (primarily the resignation of the President, or at the least

a loss in both international and national credibility). The Watergate scandal may be considered the clearest example of this contract breach, and it does teach us a lesson: those within the office of a head of state play a big role in the decision-making process, as a President may carry on his work only with the aid of his staff. The collaborators of the President (those who form his staff and who have influence over him, hence comprehending all the White House offices) clearly do not cover their position thanks to the people of the United States, that is, stating it in a formal fashion, they cannot be deemed as elected officials. Nonetheless, even without bending to the most extreme examples, and withholding a patriotic view of the President's role, it is not fully rational to assume that executive control assures the full appliance of the people's will and, even less rationally, to assume that the President (referring to the President as the President's office) acts always on behalf and in favour of the people, as many of the heads contributing to the decision-making process are not fully accountable to the electorate. Seeing the issue the other way round: executive control cannot be deemed as bulletproof, and cannot be blindly and always trusted as the only control mechanism in place.

In contrast, the opponents of presidential control deem the presidency vulnerable to interest groups, and claim that administrations affect the regulatory activity in different ways according to the Republican or Democratic provenience of the President in charge. Critics see the executive control as a mean to impose the President's agenda (being this not necessarily a symptom of bad governmental activity) on regulatory agencies. Critics, in fact, are more in favour of a legislative oversight on OIRA's activity. They deem Congress oversight as theoretically more

effective in contrasting the issue of poor accountability of the President's oversight role, as in this case the control activity is assigned to organisms composed by groups of people who are in competition between them. Critics view this as key to assure a transparent accountability of the control activity performed on the OIRA, as the competitive nature of political activity would be a natural source of more stringent and transparent control activities. The downfalls of a legislative oversight are constituted by the lack of the positive features of the presidential control that Elena Kagan listed, such as the implementation of the government's agenda and the assurance of a quick and effective action on the regulatory activity in the case of stalls or in the presence of time constraints. Furthermore, a congressional decision making process is bound to increase the costs of the overall regulatory activity, a fact that is in strong opposition with the mandate given to the OIRA. Nevertheless these views are not to be seen as definitely diametric, as both do recognise the key aspect of a need for an effective political accountability of the regulatory process and the need for a more efficient decision making process. Hence, keeping in mind the strengths of the Presidential control model, the critics moved by the opponents of this mechanism should be considered as sources to improve the efficacy of the regulatory process.

1.3. Role of politics: White House involvement in the regulatory activity

William West, in *Presidential Studies Quarterly*, states that the regulatory activity has been in fact rather responsive to presidential preferences, and that this responsiveness is more characteristic of OIRA than neutral competence.

Scholars praising the executive control mechanism tend to overly focus on the theoretical framework characterising the regulatory activity's environment. That is: the power and institutional chains descending from the President himself down to the regulatory agencies. This approach, as previously stated, tends to simplify the composition of what is defined as the President's office, which comprehends all the White House offices, such as the OMB and consequentially the OIRA. The presence of the OIRA in the President's staff already raises some questions (at least if viewing the issue from the outside) on the meaning of Presidential control. This overlapping of definitions on the roles that each agent has to take in the overseeing of the regulatory activity contributes to the blurring of the boundaries of each agent's competencies; boundaries which are, in contrast, almost dogmatically taken as valid by the most theoretic analysts of the issue.

Three main questions have to be answered regarding the involvement of the White House in the regulatory oversight activity: the first is whether or not the involvement of the executive branch of the government has favoured accountability. Note that here the reference is to accountability in general, and not to political accountability. This because political accountability is a thinner concept in respect of the general accountability to the people, and could be subject to misinterpretations

involving power and chain of command issues. And if applying the good faith concept to political accountability, the result would be that the aim of political accountability in the regulatory process is ultimately the accountability of the foresaid process to the general public; hence, at the most, the specification may be accused of overzealousness. The second question that arises from the critics moved to the presidential control model is whether or not the different actors respect the roles, and the subsequent duties attached to these, defined by the presidential executive orders. This question pertains, other than to the strict abidance to the tasks assigned to the different offices, also to the degree of respect that each office has for its principal or subordinate. The third question stems from the EO 12991, which requires the performance of the cost-benefit on the regulatory proposals which have an estimated impact superior to 100\$ million: is the cost-benefit analysis fit to ensure that the will of the electorate is fulfilled? Furthermore, is the cost-benefit analysis performed in an agreeable fashion by the OIRA?

Answering these questions requires a quantitative other than qualitative analysis of the issues, so to avoid that the differences contained in the various theories previously illustrated play a too heavy role. The quantitative insight is provided by the paper "*Inside the Administrative State: a Critical Look at the Practice of Presidential Control*" by Schultz Bressman & Vanderbergh (2006). They interviewed the top officials at the EPA (Environmental Protection Agency), being it the agency proposing the highest quantity of high-cost rules during past administrations of both political parties. The aim has been to provide a different view of the presidential control model, as Schultz Bressmann & Vanderbergh have

performed a bottom-up reality check rather than a mainstream top-down, more theoretical check. The conclusions advanced by their paper are strong enough to question the existing frameworks of the OIRA and of the regulatory process in general. Furthermore, the insight gained through the interviews of the EPA officials reveals a reality that is partially but consistently different in respect to the “mainstream” theories regarding the presidential control model. Being the aim here pursued the contraposition of the top-down based view to the bottom-up based one; to the quantitative part provided by Schultz Bressmann & Vanderbergh a theoretical and qualitative analysis will be attached, so to provide complete answers to the fore-asked questions.

The first question aims at responding to an issue that theoretically should have a straightforward answer: does the White House involvement in the regulatory overview process foster accountability to the public? Scholars, such as Elena Kagan, argue that theoretically this is case and, in addition, that the White House covers a unique institutional role which is bound to produce a higher degree of accountability in respect of other organisms.

Table D provides us with an insight on this issue. This table is arguably a slap to the theories that support the presidential control model as it is evidence based and as it involves those very people who experiment day by day the application of the presidential control model. Nevertheless one must keep in mind that the structure of the question asked to the EPA officials aims at revealing the prevalent perception of the issue, and that it does not provide an empiric evaluation.

Table D: As between the White House and EPA, which provided the public with greater opportunities to identify and evaluate how regulatory decisions were made?

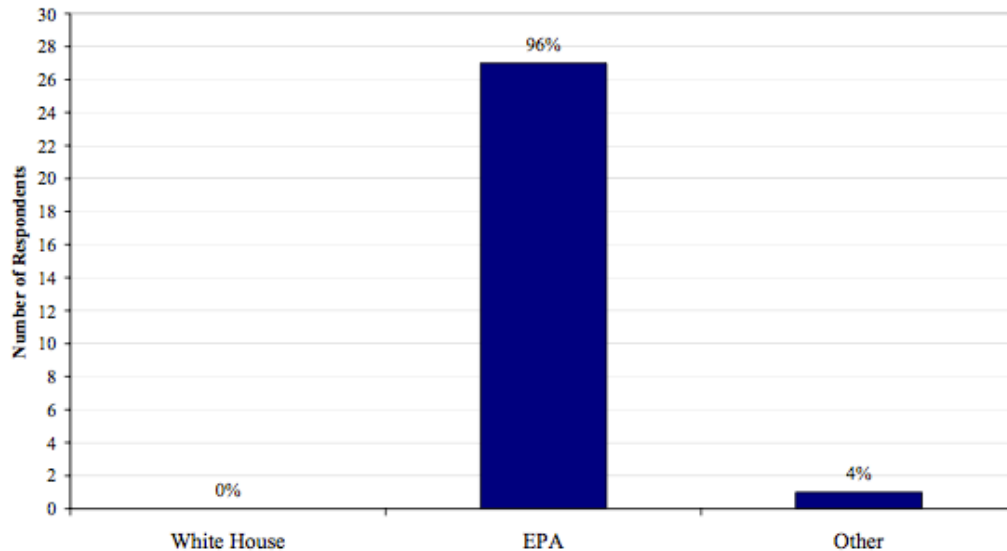
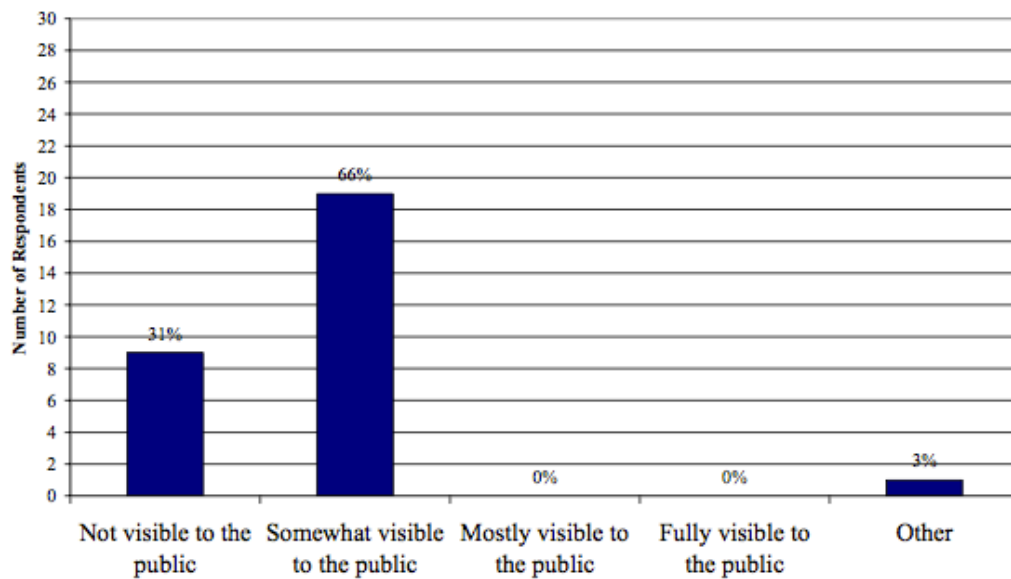


Table D shows that the 96% of the sample think that EPA has the potential to deliver to the public greater transparency and accountability in respect to the White House. Therefore, the perception of the insiders is in strong conflict with the theories sustained by scholars in favour of the presidential control model. Note that none of the interviewed thought that the White House has greater opportunities to make the regulatory process accountable to the public. The need of a greater transparency of the regulatory process, together with the need of making it accountable to the public, have been two of the principal reasons that led to the decision to subordinate the regulatory activity to OIRA's review, and consequentially to the President's office. Table D seems to invalidate this.

Table C questions whether the increased transparency objective has been met with the introduction of the presidential control model.

Table C: Which of the following would you say best characterizes White House involvement in EPA rulemaking?



According to the EPA officials the involvement of the White House in the regulatory activity is somewhat opaque. The conclusion that may be drawn from the analysis of this survey is that the Presidential control model is currently failing in delivering transparency to the regulatory process as well as in improving the overall accountability of the regulatory review process.

The second question pertains to the respect that the various actors involved in the regulatory process have of each one's task and of the others' role.

According to the mandate given to OIRA, this, and only this office, has the duty to review the regulatory proposals filed by the agencies. The executive control has to be exerted, always according to the mandate, through the role given to OIRA; that is: a liaison role put in place in order to strengthen the link between the bureaucratic administration and the government. The aim being that of fostering the transparency of the regulatory review process and of making it more reactive to the President's policy priorities. The respondents have stated that while on regulations featuring a low political salience the agency has been able to provide an effective and accountable impact assessments (through mechanisms such as the APA), it was on those regulations that featured high political conflict that their job became difficult. This due to the fact that the roles that each actor has to exert in certain occasions blurred one into another, with the effect of causing coordination and collaboration issues between the agencies and the principals. Just as the agency-principal issue (when a multiplication of principals occur) affects a marketing department of a business slowing it down, the regulatory process' effectiveness is put at stake when an increasing number of principals appear on the scene. Respondents have claimed that when initiatives deemed as politically salient are proposed various offices of the White House become involved in the regulatory process. Their perception of the issue, in addition, highlights the unexpected role that OIRA assumes in these cases. In fact, OIRA assumes at times an arbitrage role in solving the conflicts that these cases generate, carrying on a role that was not initially expected to be part of OIRA's duties. If performing a behavioural analysis on this relationship pattern, it is sound to assume that in a strongly politically affected environment, the confusion and compromise regime that arise do not help to make the whole procedure more

accountable, transparent or efficient. In fact these two characteristics that arise in times of political conflict are arguably enemies of accountability, especially when the lines of responsibility do not follow a fairly standardized and recognisable path. Furthermore, when taking into consideration that respondents deem the White House as more able than the single agency to make the regulatory process less accountable to the public, the whole mechanism in force becomes questionable, and certainly the respect and trust that each actor bears in the other actors will not be encouraged to lie at the optimal level.

The third question considers the role that the cost-benefit analysis has in the impact assessments regarding the agencies' regulation proposals. This issue poses under the lights the heart of OIRA. The regulatory review process carried on by OIRA has its foundations in the performance of the cost-benefit analysis on the proposed regulations. As previously stated, the performance of the cost-benefit analysis is the primary way to provide technical validity to the regulatory process. The aim has been that of protecting the regulations from parochial interests and that of assuring that the approved regulations would in the end be only the ones that delivered a positive cost-benefit trade-off.

Both the supporters and critics of this methodology may easily bring on arguments both in favour and against the cost-benefit analysis. The point debated here is not the efficacy of this method in comparison with other quantitative and qualitative methodologies available for the evaluation of a regulatory proposal, but

how this methodology actually works and how it is perceived to work in the current configuration of relationships among agencies.

EPA respondents advocate that OIRA poses too much emphasis and attention on costs, while not focusing adequately on benefits, and in their opinion this happens primarily because reducing the regulatory burden is seen as a prime objective by the OIRA. This may certainly be deemed as both positive and negative but, again, this shows that there is room for improvement also in the technical sphere of OIRA's review process.

1.4. Conclusions

Keeping in mind that the administrative bureaucratic process and the government are bound to collaborate respecting the independency of one another and, in turn, the nature of each of them in order to achieve the best outcome, these results do not picture an ideal state of things. The technocratic purposes of OIRA appear to be not as important as the fact that it holds a conjuncture role between the administrative and the political world. Hereafter are reported two different cases of political influence on the regulatory activity.

The first example is to be considered as the “classic” example of a political policy “push” filed by the OMB down to OIRA and in turn to the agencies: “The role

of Federal regulation in facilitating US participation in global markets should also be considered. Harmonization of US and international rules may require a strong Federal regulatory role. Concerns that new US rules could act as non-tariff barriers to imported goods should be evaluated carefully.” OMB Circular A-4, Regulatory Analysis, 2003.

This circular represents what scholars would define as a “harmonization of the measures to implement in abidance to the governmental policy”. Arguably this is a case that fully supports the presidential control model, as it provides agencies with a clear direction towards which to proceed.

The second example highlights the difficulties that arise when political conflict is high. The quality of the regulation reviews by OIRA is significantly lower in periods of high volume rulemaking such as in “midnight regulation” periods, which are to be indentified as the last six months of a presidential term. McLaughlin and Ellig (2010) demonstrated that during these periods OIRA tends to review the agencies’ impact assessments for a shorter lapse of time, and that this may be due to the high political pressure delivered to the OIRA during the final months of a presidential term (Brito and De Rugy, 2009). Another factor affecting OIRA’s regulatory review action during the midnight period might be the change of administrative processes caused by the end of the political cycle, such as personnel or budget transfers (McLaughlin and Ellig, 2010).

The OMB circular A-4 and the lower quality of midnight regulations phenomena constitute two cases of political intervention in the regulatory activity. These are proofs that in periods of political distress (end of political cycle) and in matters regarded as politically relevant (non-tariff barriers), the influence of politics on the regulatory review activity is higher than on the “ordinary” daylight activity. The fact that in the “midnight regulation” case the shortage of time is correlated with poorer quality reviews by OIRA clearly highlights the too loose boundaries of each actor’s role and autonomy. It appears as though OIRA could potentially suffer excessively from the political swirl that detonates when matters triggering political interests are at stake. It is of key importance to remind that political influence is not *per se* an handicap to the regulatory review process, but the fact that the EPA officials link the influence of the White House with a higher possibility of poorer accountability to the public is already a matter that should urge a more severe traceability of the actions that each actor undertakes while influencing the regulatory process.

Has OIRA become a political organ itself? Surely enough OIRA holds a difficultly manageable role; it has been instituted to provide rationale, technical validity and accountability to the regulatory process. Better rephrased: OIRA has been provided with the instruments (legal and technical) to implement the measures needed for the achievement all of these objectives; nevertheless, OIRA clearly does fall short in some cases. Occasionally, in fact, manifestations of a decaying balance between the technocratic aim and the political role it holds, skewed in favour of the latter, have occurred. Ultimately, OIRA’s regulatory watchdog activity may be

deemed as having been efficient in “guarding” subordinates, but as inefficient in managing the political buffer role it has suffering from the fact of repeatedly being at the centre of political conflicts, with the consequent risk of being pushed to take sides and potentially influence the regulatory activity, giving up its “watchdog” role.

II. The debate on the Cost-Benefit Analysis: Pros and Cons

The debate on the efficacy and consistency of the cost-benefit analysis is probably one of the most fascinating among the ones populating the academic literature on the regulatory process; the achievement of a complete understanding of the practices of ROBs and of the different environments surrounding them would be somewhat incomplete if not with a comprehension of the scholar literature regarding the main component of the impact assessments: the CBA analysis. In the first place, the debate aims at the very heart of the regulatory procedures, as it focuses on the effectiveness of the CBA but, most importantly, as it is directed at the whole regulatory structure embedded in the legislative configuration of a country. The debate appears quite vigorous in respect to the ordinary academic standards, and it is openly characterized by two opposite factions: those that view the CBA as the most efficient tool today available for carrying on the regulatory activity of a country, and those who advocate a total elimination of the CBA as a tool for decision-making or, in the softest cases, a profound redrafting of the guidelines that dictate the fashion of its use from the very basis.

Of course, some scholars have tried to find a middle ground between these two factions. Their proposals all have as foundation the dogma promoted by scholars such as Sunstein and Revesz stating that CBA is here to stay (Harrington, W., *et al.* 2009). This approach has its greater strength in the fact that it is the most prone to the

resolution of the conflict between the two factions. But the other side of the medal is that it chooses to completely ignore the philosophical aspects of the debate, probably in order to diminish the ideological component of the issue. This word, philosophical, is hardly to be considered as the favourite word of the majority of the economists, nevertheless one cannot escape from the fact that the philosophical aspect of an issue is to be regarded as the dark side of the moon of economics most of the times, and especially in this case.

The CBA is the main tool in used in the impact assessment practice all over the world. The necessity of hiding the subjective aspects of the regulatory activity has pushed the use of this methodology in all countries engaged in extensive regulatory or legislative review. This brings under the light the roles of both the OIRA and the IAB. These two ROBs have the duty of overseeing the regulatory activity, and to base their decisions on data that has to be the most empirical possible in order to legitimize its review job. Thus, it is easily comprehensible why the CBA has been the most used tool in drafting impact assessments: it provides a technical and numerical basis on which to perform an impact assessment review. Hence this criterion is, at least formally, in compliance with the technocratic aims of ROBs, and in contrast with the possible intromission of subjective elements in the evaluation of an impact assessment. This constitutes the why. Arguably the intentions have been all the best, but it is the analysis of the how that provides meaningfulness and legitimization to the why.

The introduction of the CBA has in fact obtained the goal of formally legitimizing the regulatory processes. And, gaining strength from this, it is now regarded as the only tool available that is able to encounter both the technical requirements requested by the executive orders issued by the President of the United States and the need to improve the efficiency of the EU regulatory process. Nonetheless, the critics of the CBA advocate that the economic premises currently attached to the practice of CBA do not constitute an effective response to the causes that requested its implementation in the first place.

The claim advanced by scholars in contrast with the use of CBA is the following: they argue that the CBA method inappropriately values the impacts on “priceless” species, habitats, and other important, difficult to quantify resources, that the discounting of future regulatory consequences, including human mortality, treats lives unequally and trivializes the future, and that gains and losses to the rich should not be treated the same as those to the poor (Ackermann & Heinzerling, 2004).

Here are enounced three of the various points on which the critics of the CBA focus upon. The first point pertains to the way in which benefits and costs are calculated, the second to the absence of the consideration of distributional issues in calculating the costs and benefits in relation to the composition of the population, and the third to the process of attempting to monetize everything, even those things which in the critics’ opinion should not be monetized, as the value of habitats, species or health.

The first is a quantification issue. The critics argue that often a large part of the benefits of a regulation cannot be quantified, especially when these are environmental regulations. If, for instance, an impact assessment reports only how many cancer cases will be averted but it does not report the impact of other illnesses or the effects on the environment, the impact assessment will be seen as fully incomplete (Heinzerling, 1998). The second point refers to the impossibility of the CBA analysis to understand and take into the consideration the diversities of the population. The CBA assumes, in its premises, that there are no differences in the willingness to pay among people, therefore standardizing in a sense rather than in the other the population's diversities. The distributional issue is one of the major critics moved to the CBA method as, if viewing the problem even from an only partially philosophical perspective, a wall to wall argument will be likely to take place among opposite parties, and it would indeed be a loud argument, as it would be charged by ideological diversities. One of the main points of the detractors is that the willingness to pay of people is, other than diverse among the population, also different if taking into consideration the value of public goods or private goods. One of the main differences regarding the value of a private good is, for example, the dread associated with the possibility of damage to a private good. The difference could be well explained by a simple example: if a regulation is estimated to cause a increasing of cancer disease x million of 1% in Asia, then probably the people of the US would pay a relatively low sum. But if the effect were to reveal itself in the entire world, even in a smaller percentage, say 0,5%, the willingness to pay for the rejection of the regulation would be higher. This because of the dread component that would in this case have a place among the drivers guiding the willingness to pay of the US

population. The third critic reported from Ackermann and Heinzerling is the tendency to monetize everything. Again, this is surely to be deemed as a need for the overall accountability, transparency and effectiveness of the ROBs, but it is worth to carefully weigh the benefits and consequences of this race to formally high standards. The example of the value of a human life is the most appropriate to describe the critic moved to the CBA. In the modern practice of the evaluation of health impacts that a regulation or legislative initiative is expected to produce on the population, the use of the statistical life criterion has become widely used. The statistical life value is, in a nutshell, the amount of money that people would pay, or accept, for the increasing of the risk (of death, cancer etc.) of one per million. As stated previously, this kind of estimates of willingness to pay are essentially flawed, as they do not take into consideration the emotional component that instead would have a sensitive impact on the real willingness to pay. Harrington, Heinzerling and Morgenstern, in *Reforming Regulatory Impact Analysis 2009*, identify three main flaws of the statistical life method:

- i. The statistical life method ignores completely the real issue at stake: it does not identify the true value of a real life, and CBA critics believe that this method is just an attempt to go around the issue.
- ii. In assuming that the people's willingness to pay is the true measure of value, CBA takes as granted that the decisions made in private economic markets would be the same as those made by individuals acting as public citizens; the difference in fact may well arise especially in matters

regarding the individual sphere of one's life such as the health related issues.

- iii. The third point features the critic that more than the other strikes at the heart of the debate: the valuation of life or health according to the willingness to pay, which, according to the critics, is a method that calls for inequality. This because rich people would pay more than poor people and, following the line of reasoning of the willingness to pay criterion, this would lead to a higher evaluation of the rich people's life. Fact that is, oddly enough, in compliance with what CBA proponents have advocated; nevertheless the question to be posed is quite striking if asked in childish terms: does one have to value more the life of a person only because it has more money to pay for it? This point is also linked with the attempts of attaching a minor value to the life of elderly people in respect to youngsters, and more in general to the life of people living in poorer countries.

The danger of placing a high value on the criterion of statistical life is quite frankly obvious, although in fact the US population could be generally the one that would benefit the most (or pay the least) in respect to the population at large from this approach. The point is that the differences in the willingness to pay are big enough to cause questionable results also within the boundaries of an advanced country such as the US. The difficulty of implementing a measure aimed at

identifying and take into consideration the variability in the willingness to pay, placing a value on possible differences in distributional impacts of regulations, is nevertheless to be recognised. Ironically, this has as well pushed the debate to philosophical terms, making the quest for an acceptable middle ground very complex.

Another element of the CBA causing perplexities among the critics is the practice of discounting. The claim here is that “although discounting does account for the costs to present generations of providing these protections, opponents of CBA believe that discounting is not consistent with environmental law’s forward-looking premises because the standard technique of constant exponential discounting can have a potentially large adverse effect on the perceived benefits of policies – such as policies to address climate change or policies to protect against long-latency diseases like cancer – that aim to prevent future harms” (Harrington, W., *et al.* 2009). Therefore the point is that the discount factors employed in the CBA may not take into account the possible increasing return to scale nature of environmental issues or already present but non visible health problems (is it in line with the theoretical aims of CBA not to discount possibly existing cancer diseases until the time of its diagnosis?).

Transparency is yet another aspect of the use of CBA that makes the critics twist their noses. The transparency aspect of the regulatory process here finds its second dimension: the first is the one regarding the external environment of the impact assessments: hence all those ways in which impact assessments can be

pushed around and shaped by the actors of the regulatory process, the transparency of the previously listed procedures, and the possibility of making these accountable to the public. These issues have validity also in referral to the IAB framework, although in different ways, as it will be explained in the following section. The second dimension is the internal transparency dimension of the impact assessments: the comprehensibility of the analysis contained in an impact assessment. Too often the comprehension of what value is attached to human life, or of what discount rate has been adopted in the performance of CBAs is impeded even to well-trained eyes (Harrington, W., *et al.* 2009). Thus, taking into consideration that the accountability of the regulatory process would be mutilated both by the non-transparency of the main tool for decision-making and by its absence, this issue has become as well a primary debate ground for critics. For the impact assessments to be a tool for improving not just the decision-making process, but also the accountability to the public of the regulatory process, critics suggest that impact assessments should be preformed also to justify when the decision of not to regulate is taken. This recommendation aims at expanding the current standards adopted by the agencies and by the OIRA, requesting the performance of impact assessments on both the regulatory/deregulatory actions and the decisions of not to regulate when the estimated impact of a proposals exceeds the \$100 million benchmark. Olson (1984) suggests that this one-sidedness of the regulatory review process potentially introduces a bias against regulation. This is in fact a quite straightforward step that the Presidency should have undertook in order to serve to the maximum extent possible the accountability purposes of the regulatory review process. The fact that this measure has not still been implemented, although its usefulness to the purpose of

accountability is difficultly contestable, is in line with what Wendy Wagner suggests in *Reforming Regulatory Impact Analysis* (2009): “the design of a RIA is purposely structured to make the impact assessment a litigation support document, and not a tool to provide guidance for decision making and accountability of the process”. The deduction process here is not truly consequential, and therefore it has to be taken with all the caution possible; the suggestion made considers only the fact that the behaviour of the Presidency in this specific case (the decision to ignore the critiques moved by Olson), nevertheless this is arguably more in line with Wagner’s view than with the mainstream scholars’ one. Wagner’s suggestion is also supported by the fact that US impact assessments (and also EU’s) systematically lack the presence of counterfactuals, that is: the consideration of the diverse possible realities that could stem from a regulation, deregulation, or from a decision of not to regulate. The result is the creation of an insurmountable obstacle for a complete understanding of the relative benefits and costs delivered by a decision to regulate or not, as these may not be compared to other scenarios.

A clear example of the biases that have risen due to the overall opaqueness of the system is provided by a case study carried out by Catherine O’Neill. The study involves an analysis of the causes of the consequences that have been produced by a regulation proposed by the EPA regarding the control of airborne mercury emissions. In 1990, as part of the Clean Air Act, new MACT standards were decided and then promulgated; the EPA subsequently promulgated other rules, always under the MACT standards, in the late 90s. In 2003, the agency began to draft a regulation regarding in the specific the emissions from electric plant generation, again the

standards and benchmarks that were to guide the drafting of this new regulation were to be found in the MACT. The top management of the EPA subsequently stopped the drafting of this regulation, and requested that it was to be drafted a new regulation based on the cap-and-trade policy modelled after the sulphur dioxide trading program for fossil electric plants. Until now economists would not have got a clue of the possible consequences that have raised from this change of route, but the consequences of this decision are public, and from these it is to be understood what this change of route has meant. Taking into consideration the timing of the promulgation of the regulation, that is: 2007 for the first version and 2018 for the second; the results couldn't be more striking. The MACT rule would in fact have demanded the reduction of about 90% of mercury emissions already in 2007, the year of its promulgation, while on the other hand the new rule will achieve a reduction of 70% of the emissions not earlier than 2030.

The differences are so evident that no scientific paperwork would be needed to assess their magnitude. This case embeds all the flaws that could be possibly enounced by the critics of the CBA, and having a look to the consequences certainly does not strengthen the arguments of those in favour of it. The main points that deserve to be mentioned are two. The first is that it is clear that the CBA does not always work for the good of the population, as the MACT rule featured a high amount of difficultly quantifiable benefits (health related issues) and high easily quantifiable costs, and on the other hand the new regulation featured high quantifiable benefits and high difficulty quantifiable costs. The "difficultly quantifiable" concept refers directly to the use of methodologies akin to that of

statistical life which have their very basis in the standardization of the willingness to pay of people and that do not take into consideration the distributional issues among the population. The second point is that of making accountable to the public the decisions regarding which regulatory actions have been undertaken. If the decision of not to implement the MACT rule were accompanied by an impact assessment specifying why it was not enacted and what were the possible future scenarios (which were already known to the EPA officials) that would subsequently have come to reality, then a confrontation of the two rules would have been immediately possible.

In conclusion, the statement of Wendy Wagner claiming that currently the impact assessments serve as a tool for litigation is worth of further investigations, although at the moment it is to be deemed only as a suggestive opinion. Furthermore, the advantages and disadvantages of the CBA are to be considered both when considering the technical requirement necessities, that constitute the basis for the OIRA review work, and when referring to the broader environment in which CBA has a role: the accountability and transparency necessity, and its weight in the final decision-making process. Both the roles and operates of OIRA and IAB cannot be understood if not with the comprehension of the CBA debate and its application in the analysis.

III. The Impact Assessment Board

III.1. Introduction to the IAB

The impact assessment tool is to be considered, ultimately, as a relatively new actor in the EU legislative panorama. The recent changes of the procedures involving the drafting of impact assessments are in fact the first proof of the juvenility of the mechanism. To use a metaphor: after buying the car and putting gasoline in the tank, the EU Commission realized in 2006 (under Barroso I) that it was time to undergo a revision of the engine. Thus, following the results of an *ex post* evaluation of the impact assessment system, the European Commission decided to establish an independent board for the review of the impact assessments' quality: the Impact Assessment Board (IAB).

The first attempts to introduce a formal procedure for the performance of impact assessments in the European regulatory activity go back to 1998 (Renda 2006); but it was not until 2002 that the European Commission took action in order to formalize the position that was to be held by the IAB. The role given to the IAB, as provided by the Better Regulation package, has been since then that of performing a review of the impact assessments filed by the DGs. As in the US case, the impact evaluation of proposals in the EU has not a coercive force in the final decision-making process, but only an advisory role. This is in strict compliance with the principles of democracy in general and, furthermore, with the unique nature of

the EU that, if possible, should stress even more the principle of the auto-determination of peoples, so dear to the history of the EU. This aspect is also pointed out by various formal EU Communications such as, for instance, the general principles of the Inter-Institutional Common Approach to Impact Assessments (IA), with point six stating: “Careful consideration of the evidence presented in the impact assessments should allow the relevant institution to decide on whether to proceed with the proposal or amendment and/or to shape the proposal or amendment in the light of its potential impacts. Impact assessment is an aid to help the three Institutions (the Commission, the Parliament, and the Council) to reach a properly considered decision. It is in no sense a substitute for political decision in the democratic decision-making process”.

After a 2-year trial period the impact assessment evaluation system was formally put in place in 2006, and provided with more exhaustive guidelines and with the mandate of giving stronger emphasis on the quality of the cost-benefit analysis (Cecot, C., *et al.* 2008). As previously stated, in the US the condition for the exertion or not of the RIA review by the OIRA is subordinated to the expected impact of the proposed regulation. In the EU framework the benchmark is not akin, or at least it is no more so. Originally, in fact, it was more alike; the process was not characterized by a strict top-down procedure, as it is now, but it involved more steps: the Commission instructed the DGs to prepare preliminary impact assessments in order to deliver an overall idea of the estimated impact of the proposals. The Commission then scrutinized these, and selected from the bouquet those initiatives that were likely to have a considerable impact in economic, social or environmental

areas (the three pillars), and subsequently instructed the DGs to perform a more in depth analysis called extended impact assessment (Renda 2006). The procedure path thus used to involve a higher number of formal steps and, more likely than not, it used to make the criteria adopted by the Commission in selecting the proposals that were deemed among others as eligible for being accompanied by a more in-depth impact assessment clearer, though probably less efficient. This primarily because a higher number of formalities naturally generates a higher possibility of enhancing the overall accountability of the process taken in consideration. The criteria that the Commission now uses for deciding which proposals have to be accompanied by an impact assessment is arguably more obscure. Now, this is not to say that the Commission presently decides on the basis of convenience or bad faith, but it is undeniable that the sources of these decisions are now potentially more hidden to the public. The proposals that have to be subject to an impact assessment are in fact decided *ex ante*: the Commission states in the Annual Policy Strategy and in the Work Program which legislative initiatives are deemed important enough to deserve additional attention by the Commission.

The parameter that now dictates the presence or not of a proposal in the Annual Policy Strategy or in the Work Program is not an empiric one (as the annual \$100 million estimated impact in the US), but it is a more subjective one. The allocation of resources to the various impact assessments that have to be drafted is guided by the proportionate analysis principle, which correlates the degree of thoroughness to be respected and the amount of resources to be employed in the performance of the impact assessment to the importance of the proposal at stake.

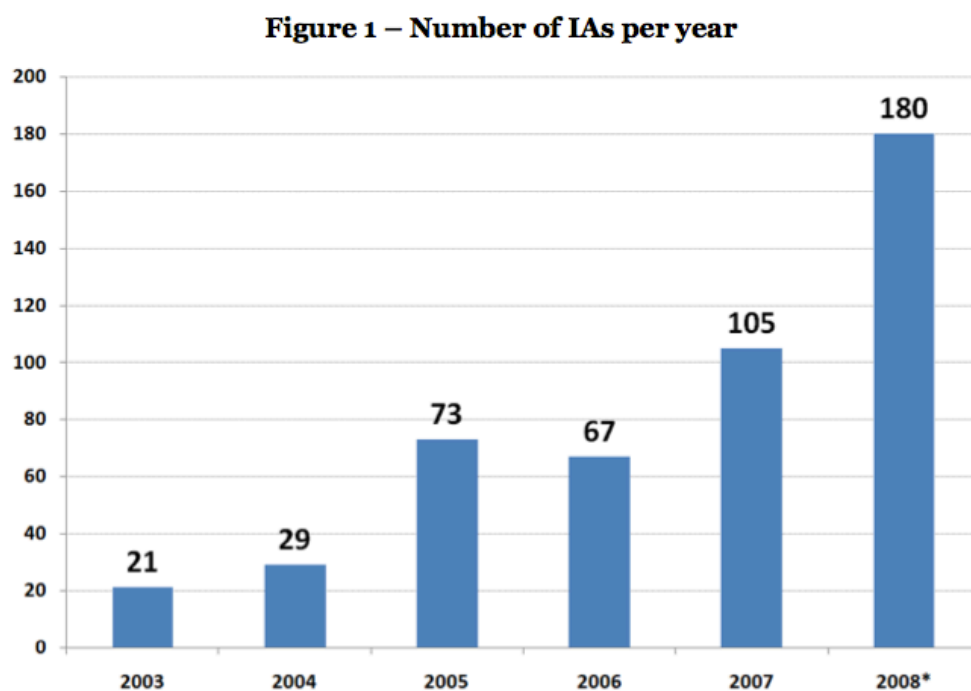
Similarly to what happens for the US case, also in the EU bureaucracy there is space for the DGs to consult the parties that are interested in the proposal, allowing them to gain a higher knowledge of all the possible impacts arising from the proposal in question. The DGs hence, as the US agencies, have as well the duty to play the information collector's role while drafting the impact assessment. The procedure is completed when the legislative proposal, accompanied with the drafted impact assessment, is sent to the Council and the Parliament.

A major difference between the tasks assigned to the IAB and to the OIRA is that of the scope of their actions: in the US, only the regulatory process is subject to the influence of the OIRA, while in the EU all binding and non-binding legislative initiatives are subject to the IAB's check. This difference stems directly from the separation of power regimes of the EU and US. In the US, as provided by the Constitution, the legislative power is a unique prerogative of the Congress, and the incorporation of the regulatory process under the executive branch is the only exception to this rule: the Congress in fact decided years ago to spin off this area of influence to the executive branch. The reasons of this decision do not pertain to that area of the debate that is hereby addressed, hence no auxiliary investigation will be carried on; furthermore, it would result a rather anachronistic specification. In the EU the scope is much broader, as previously stated. This because the IAB and the DGs have been placed under the command of the Commission, which is charged with the task of drafting both binding and non-binding legislative initiatives. There is thus a significant diversity among the separation of power regimes in force in the EU and in the US. But, before addressing this point, the role that the Commission plays within

the EU framework is to be clarified. The Commission is the organ that has to propose and draft the EU legislative initiatives, and its role may be deemed as incorporating both the executive and legislative powers. Of course, the final promulgation of laws is a task assigned to the Council and to the Parliament; hence the previous consideration is not entirely precise. Nevertheless, apart from the final decision-making process, the Commission's role glides between both the executive and the legislative power areas. The President of the Commission is in fact often referred to as the Prime Minister of the EU; in reference not to his actual role, but to the important and relevant role that the Commission detains within the EU framework. This specification has as aim that of avoiding to interpret the Commission as a bureaucratic organ as, although it does have some of the characteristics of a bureaucracy, including that of having non-elected officials at its top (in contrast with the OMB, which is posed within the office of the President), it is empowered with heavily powerful tools and with a high degree of autonomy. Going back to the differences between the two power separation regimes, it is clear that in the US this separation is more abrupt, while in the EU it is more "soft". This, and the fact that the IAB is under the influence of an organ that does not contain *per se* assurances of accountability, are the major issues regarding the EU regulatory framework.

III.2. Quality of EU impact assessments

The best starting point for the evaluation of the quality of EU impact assessments is having a look at the empirical data. The first table shows the number of impact assessments performed per year from 2003 to 2008 (Renda, A., 2008).



Source: own elaboration on data from the Commission's IA website (Commission estimate for 2008)

The second table shows the mean impact assessment scores on index by year, from 2003 to 2007 (Cecot, C., *et al.* 2008).

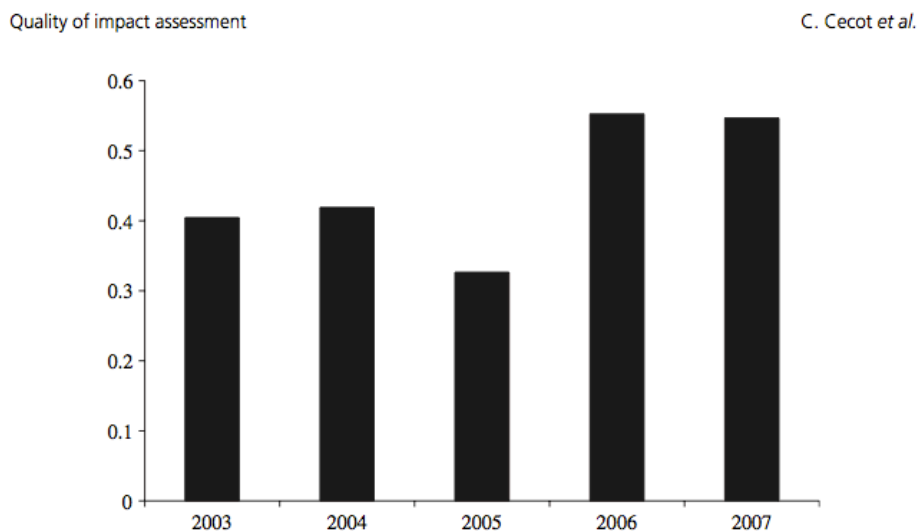


Figure 1 Mean impact assessment scores on index by year.

Notes: For 2003–2007, the number of observations summarized is 15, 21, 29, 21, and 25, respectively.

The combined analysis of these two data sets helps assessing if the objectives set to the IAB of increasing the quality and efficiency of the regulatory process have been met.

The numbers provided by these two tables do encourage a certain optimism; in fact it appears as though both the quality and the quantity of the impact assessments performed under the watch of the IAB (that is from 2006 onwards) have been improving, at least until 2008. Furthermore, there is evidence that the quality of impact assessments has increased together with the relevance of their respective regulations, in abidance with the proportionate analysis principle (Cecot, C., *et al.* 2008).

The European Commission's Impact Assessment Board Report for 2012 provides more up to date data.

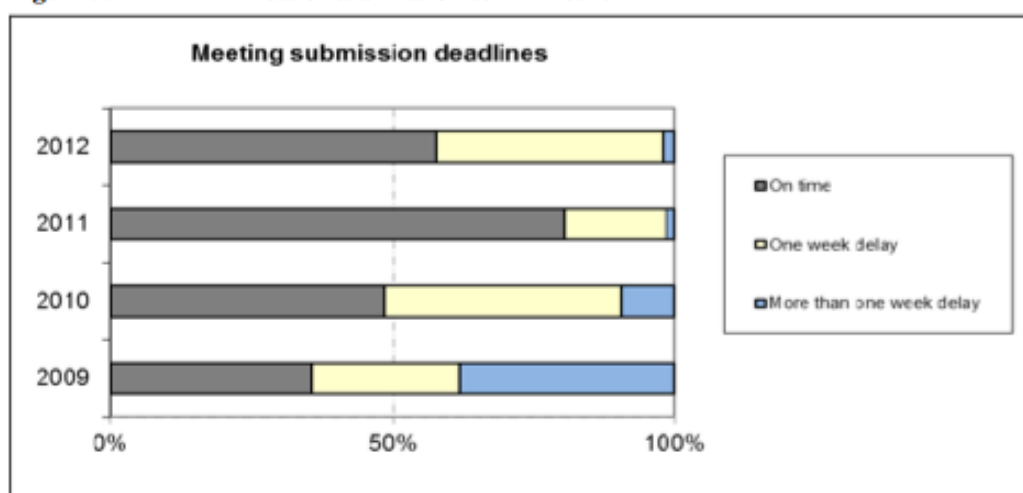
Figure 5 - Board key activity statistics, 2007–2012

	2007	2008	2009	2010	2011	2012
Impact assessments						
Total impact assessments examined	102	135	79	66	104	97
Legislative proposals	57	86	53	49	80	76
Non-legislative proposals	45	49	26	17	24	21
<i>Share of legislative proposals</i>	56 %	64 %	68 %	74 %	78 %	78 %
Opinions						
Number of opinions issued	112	182	106	83	138	144
On the first submissions	102	135	76	64	103	97
On the second submissions	10	43	30	18	34	44
On the third submissions	0	4	0	0	1	3
On special case submission	0	0	0	1	0	0
Number of opinions requesting resubmission, after first submission	9	44	28	27	37	46
<i>Resubmission rate</i>	9 %	33 %	37 %	42 %	36 %	47 %
Procedures applied						
Number of meetings	22	26	21	23	25	20
Cases in oral procedure	57	101	67	57	78	81
Cases in written procedure	45	34	12	7	26	16
<i>Share of oral procedures</i>	56 %	75 %	85 %	89 %	75 %	83 %

Comparing the numbers it is clear that table one's numbers (Renda, A., 2008) were in referral to the number of opinions issued by the IAB. If taking this measure as the standard for the numerical performance of the EU regulatory review process, it is clear that the quantities have continued to increase; with the only exception being 2010 and 2009, as in these years the number of Commission proposals had dropped due to the transition from one Commission to the other. Nevertheless, the numbers reached in 2008 have yet not been matched. What has been quite steadily increasing

is the resubmission rate: the percentage of times that the IAB filed the impact assessments back to the DGs. The increasing of this parameter means mainly two things: that the standards required by the IAB have increased, or at the least remained put, and that the quality of first submissions is still highly variable. Another measure identifying whether the efficiency has increased, and whether the relatively new practices have been absorbed by the DGs is provided by figure 9 (European Commission's Impact Assessment Board Report for 2012), showing the timeliness of the submission of impact assessments to the IAB.

Figure 9: Timeliness of submission to the Board



The results clearly indicate that the practices have been interiorized by the DGs, even though the 2012 performance has been worse than that of 2011 (also in reference to the larger resubmission rate). The Commission's Communication on the second review of Better Regulation in the EU (2008) assessed two major areas of improvement: the successful mainstreaming of impact assessments in to the policy cycle of the DGs - thus the achievement of a cultural change - and the performance

of a significantly higher number of impact assessments (Renda, A., 2008). These results are currently being confirmed and pushed beyond their previous horizons, especially in referral to the cultural change aspect, as figure 9 denotes.

The Commission's 2012 IAB report nevertheless identifies a number of areas that could be in addition targeted in order to further increase the efficiency and effectiveness of the EU regulatory process. However, only a few of those areas have been decided to be addressed; and these are primarily the improvement of the Commission's capacity in implementing its public policy objectives, and the reduction of the unnecessary regulatory burden. These issues are specifically targeted by the Regulatory Fitness and Performance Program (REFIT), as announced by the Commission in its Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on EU Regulatory Fitness (December 2012). The Communication states: "The REFIT process will start with a mapping exercise to identify the regulatory areas and pieces of legislation with the greatest potential for simplifying rules and reducing regulatory cost for businesses and citizens without compromising public policy objectives. Normally, the mapping will point to areas where further evaluation, including of costs and benefits, is needed..." This is simply another way to state that the existing regulations and pieces of legislation will be reviewed with a stricter focus on costs and benefits. CBA analysis is not directly mentioned by the Communication, but it does seem that the reference is to more analytical and prone to monetizing methods. In a certain sense, the REFIT calls for a harmonization of the EU regulatory and legislative process with that of the US,

posing a greater value on quantitative methodologies in the performance of impact assessments.

Also in the EU case, the large part of the mainstream studies focus on the external environment of the impact assessments. The questions regarding the actual methods employed by the DGs in the performance of the impact assessments are only marginally addressed; especially from the Commission's communications. Also in this case there is an objective difficulty in assessing, *ex post*, the quality of the impact assessments, being it for the fact that at times IAB's discussions occur behind closed doors, or being it for the fact that the evaluation of the impact assessments by independent agents is made difficult because of the not determinant role given to empiric methods; and, as argued in section two, the possibility of performing reliable *ex post* evaluations is key for fostering accountability and transparency, other than for evaluating the actual quality of the impact assessments. As for the US case, also in the EU there are big questions regarding the use of monetization and quantification techniques. Nevertheless, the debate regarding the EU regulatory environment is not as harsh as the one referring to the US regulatory system. This is rather peculiar, as in fact the techniques employed by the DGs are the same as the ones adopted by the US agencies (such as the CBA). The point that probably attenuates the EU debate is that the role assigned to the quantitative techniques is, at present, not as central as the one they have in the US regulatory framework. In turn, this has had probably the effect of diminishing the ideological-philosophical component of the issue, consequentially superficially softening the tempers of the two parties. The issues at stake are nonetheless the same, and the absence of an

accountable head in the EU regulatory process (meaning that the President of the Commission is not strictly speaking an elected official), and the launch of the REFIT program do represent a good basis for the formulation of questions that sooner or later will have to be answered.

III.3. Role of politics: accountability

Radaelli and Meuwese (2008) argued that the future of impact assessments in the European Commission would eventually face a number of questions, mostly regarding the need to define who controls the policy process. Well, since then these kinds of questions have been asked by an increasing number of scholars. Nonetheless there are no official answers, and certainly no action has been undertaken, ever since, in order to improve the traceableness of accountability in the European Commission. The point here is that other than the question of who should be hold accountable for the regulatory process, which is already one that deserves an immediate response, there are also doubts on whether someone should be accountable within the European Commission or whether the burden is left all on the shoulders of the Parliament. Thus, other than not knowing where to look, one does not even know if to look. The issues regarding accountability in the EU case all revolve around the same point: the lack of the presence of elected officials in the EU legislative regulatory process. Taking a step back, this absence of elected officials may find some counterfactuals in the Italian bureaucratic framework. For instance, the

population does not directly elect the Italian Minister for education: the Prime Minister appoints it; hence he is not, strictly speaking, an elected official. This has also value for the President of the European Commission, as the procedure leading to its appointment is not conceptually unlike. The differences nonetheless are huge, to use a euphemism. The point is that the Italian Ministry is directly under the authority of the Prime Minister; and, in this case, the similarities are to be found more in the OIRA case than in the EU one. The autonomy that is granted to the European Commission is instead, as previously discussed, very large; both in its actual independency from other bodies and in the legislative area. The European Commission in fact does not appear to be similar to any other body: it features a unique structure and a unique degree of empowerment (not in the sense of broadness, but in that of comprehending a multitude of aspects). This may be an important matter of debate but, focusing back on the role it has in granting accountability to the legislative regulatory process, it is indeed clear that the roles should be more defined and possibly explained by the European Commission. This should be such a basic matter that the fact that no one may be deemed as accountable for the EU legislative regulatory process is striking. As in the US case, if one divides the concept of accountability in two areas: political accountability, and accountability to the electorate, then probably the European Commission could be ultimately viewed as accountable. In which sense? Needless to say the only sense in which the President of the Commission can be deemed accountable is in the one having a political connotation. To ease the comprehension of this concept: he may be deemed accountable only to the European Commission itself, or to the other European bodies; but not to the population. In child's words: the population has no direct (and

realistic) possibility to control the Commission, which instead has an enormous degree of authority on it.

Thus, the final accountability to the people of the EU legislative regulatory process is not clearly there. One of the major points in favour of this is the subjectivity component characterizing the choice of the initiatives that should undergo an impact assessment check. This is not a point that is openly stated by the European Commission, it is rather to be understood reading between the lines. Renda, in “Advancing the EU better regulation agenda: selected challenges for Europe (2008)” states that the most reasonable interpretation of the Impact Assessment Guidelines is that the need for impact assessments is independent from the inclusion of an initiative in the Work Program. In particular, he poses the focus on the fact that given the absence of precise criteria, the accountability of the Commission for having included/excluded an initiative from those in need of an impact assessment is substantially reduced. The European Commission’s Communication “Inter-Institutional Common Approach to Impact Assessment (IA)” states at point 11: “The proposals submitted in its Annual Legislative and Work Program will, as a general rule, be accompanied by an impact assessment...” The specification “as a general rule” seems to be placed there for the very purpose of supporting Renda’s suggestion. Now, if this is the case, there are grounds for the intromission in the procedure of a subjective component that could potentially cause the reduction in the process’ transparency and accountability; just as in the US the decision of “not to regulate” is. This subjective component features both upsides and downsides. The upside is certainly that of quickening the whole regulatory process.

This happens by scaling down, in respect to the procedure previously in force, the number of relationships that have to be entertained both in the decision of which legislative proposals are to be included in the Annual Policy Strategy and the Work Program, and in the number of formal steps that have to be dealt with in the drafting of the impact assessment. Stated in a more minimalistic way: the main advantages of the procedure now in force are the diminishment of the red tape and the improvement of the efficiency (regarding the time frame) of the process.

Another peculiar component of the EU regulatory framework is, as previously stated, the particular marginal role given to the quantitative analysis in respect to the qualitative one as a tool for performing impact assessments. This superficially allows the EU regulatory framework to escape from the critics mentioned in section 2, as in fact it has done. But, on the other hand, the accountability of the process is, surely enough, handicapped by the fact of not subjecting the opinions of the IAB to empiric parameters; fact that in turn generates a difficulty in evaluating its operate.

III.4. Conclusions

To quote Hans Magnus Enzensberger: “As if the 19th- and 20th-century battles over constitutionality never happened, the Council [of Ministers] and the [European] Commission were agreed from the very beginning that the people would have no voice in the European community's decisions.” Furthermore he states that: “the European Parliament is no more than a fig leaf for a paternalistic nomenclature”, and that “The Parliament is helpless vis-à-vis the real locus of power, namely the Commission's cabinets and directorates-general”. Of course, this is just an intellectual’s opinion, but when he argues that no citizen in Europe could possibly read the *acquis communautaire* at 150000 pages, it’s hard to say that he hasn’t got a point. Still, there are many that view the overwhelming power conceded to the European Commission as too loosely subject to public control and, more likely than not, the analysis of legislative regulatory process and framework does not point in an opposite direction.

IV. Conclusion

In order to better explain the conclusions that can be drawn from the analysis of the OIRA and of the IAB, the flaws of the methodologies for assessing the impact assessments' quality will serve as a starting point in explaining the flaws of the regulatory oversight bodies and of the respective regulatory processes analyzed.

The methodologies for assessing the quality of economic analysis are currently three (Cecot, C., *et al.* 2008):

- i. The first is using experts to analyse the quality of an analysis.
- ii. The second is using an empiric benchmark, such as cost-effectiveness measures, or broadly speaking of parameters, to assess the abidance of a given impact assessment to acceptable technical standards.
- iii. The third is to use a “scorecard” to assess whether the analysis has met key requirements.

All three of these methodologies are currently being used for the evaluation of the quality of both EU and US impact assessments. The methodologies here enounced

feature an increasing degree of empirical validity, in reference to the possibility of a replica of the obtained results by other subjects.

If adopting these methodologies in the evaluation of the overall US and EU legislative process, the major flaws that affect these methods, when used for the review of the quality of a single impact assessment, keep their meaningfulness even if in reference to a different entity. If the subject of the analysis is to be the review of the effectiveness of the EU and US bureaucratic decision-making process, the foresaid flaws do have a role in helping to identify which of these flaws could potentially affect these bureaucratic frameworks.

It may well seem as if these concepts were pushed to their validity limits, but the analysis of the three methodologies in fact reveals herself as fit to explain the pitfalls of both the impact assessments and of the bureaucratic frameworks. If these similarities were to be used for the evaluation of the decision-making process, regarding the choice of which legislative initiatives are to be accompanied by an impact assessment, then the identification of the flaws that affect these frameworks is at the least eased; and the conclusions made more agreeable with.

Most scholars think that in order to abide to the scientific method, all three methodologies should be used when reviewing an issue in order to achieve a complete and consistent review. Nevertheless, the methodologies adopted in the EU and in the US are respectively the first and the second of the three previously enounced; that is to say, the use of experts in the EU case, and the use of parameters

in the US case. The flaws of these two methods are respectively the possibility of linking the results of the inquiry too tightly with a subjective component and, for the second case, the fact that the analysis will be overly subordinated to the amount of information available at the time of the study, meaning that the *ex post* analysis is too much tied to the accuracy of the initial information (Cecot, C., *et al.* 2008). These, in fact, represent the first sources of uncertainty in the regulatory processes of the respective countries' frameworks, in the sense that these flaws are the ones giving birth to the first obstacles for the complete transparency of the legislative process. The accountability of the regulatory processes is strictly linked with its transparency and, in addition, the junctures of a formal bureaucratic structure that are not fully transparent (or that have the potential to be made more opaque) are those that are more likely to prevent a full accountability of the process to the public.

The sources of the Commission's decisions on which of the proposals have to be accompanied with an IA are, with the enforcement of the new procedure, exposed to possible biases caused by subjective mistakes. The procedure now in force is not to be deemed flawed, but it is to be deemed vulnerable to this class of biases. It must not be forgot that the whole regulatory and legislative process of the EU must serve the same democratic accountability principles that the OIRA has to serve in the US, even though the perceived bureaucratic nature of the EU could mislead each of us. Hence, the presence of a possible source for biases in the procedure, such as the lack of accountability, is certainly a problem that has to be dealt with in spite of the fact that biases have or have not already occurred or risen to the attention of the public. Ultimately, it is an issue caused by the consequentiality of

the legislative procedures as, as already seen in the case of the OIRA, the execution of the impact assessments on highly political initiatives could potentially influence in a not originally intended fashion the decisions of the Council and of the Parliament. This is furthermore strengthened by considering that the EU impact assessments are as well based on the performance of CBA, and on all the potential advantages and disadvantages that this type of check carries with it.

Nevertheless, if in the EU case the source of the lack of transparency is to be found in the premises of the impact assessment procedures, in the US case the source is to be identified in the framework of the impact assessment procedures. In the US the source of uncertainty is strictly tied to the use of parameters in the evaluation of impact assessment: if the *ex post* evaluation is highly tied to the initial available information, as it in fact is, making accountable all the pressures and actions that play a role in between the initial estimate and the final drafting of an impact assessment is to be regarded as paramount in order to execute a correct and consistent *ex post* evaluation of the impact assessments. Most of the difficulties encountered by scholars in studying OIRA's and IAB's work stem directly from the impossibility of eliminating from the final impact assessments the "sound" of the institutions' influence on the process, therefore preventing the execution of a consistent check on the regulatory review procedure.

OIRA is currently to be deemed more fit than the IAB to meet the accountability standards theoretically required by democracies, being it because of its greater capacity or expertise, or because of the higher amount of rules that

regulate its interaction with the agencies and with the public. This is primarily due to the fact the system in place does not contain, strictly speaking, elements that make the regulatory system inefficient and opaque. Rather, the system could be exposed through the OIRA to political pressures that could have the potential to temporarily shape in its favour the relationships between the agencies and the OIRA and the White House; actions that have the potential effect of creating inefficient results and, furthermore, to make the drafting of the proposal and the impact assessment procedure less transparent and less accountable. The EU regulatory framework seems to be exposed, on the other hand, to biases which stem from its inside, that is directly from the premises that drive the tasks assigned to the IAB and to the DGs. This because of the subjective biases that could occur in the initial stages of the process, or because of the conflict of interests that could touch the members of the IAB that, even though repeatedly addressed by EU public relation activities as independent, cannot be excluded from being defined as vulnerable to conflict of interests. Furthermore, the question of the role that is currently being held by the Commission in the EU framework represents the corollary potentially permeating every aspect of the IAB's role. Ultimately, it seems that the US regulatory framework may be vulnerable to occasional biases and fit for the ordinary activity, and that the EU regulatory framework contains elements that could potentially lead to more systematic biases.

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