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REGULATION CHECKLIST: Common Pitfalls in Regulations

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Introduction

Federal regulations are mandated by the executive branch of the federal government and are used to implement, in some cases to finely tune, laws from Congress. They reach most aspects of American life and touch every single individual in some way. The U.S. federal government creates an average of about 4,000 final regulations each year with about 500–700 reviewed by the White House (the Office of Information and Regulatory Affairs). Of those reviewed, between 45 and 75 have significant economic impacts.[i] Most of the time, people that comment on regulations are those who feel directly impacted by those regulations, usually because they impose either a large cost on them or their company, lead to a loss of liberty, or because they address a problem that people feel deeply about. [1] But for most Americans and, in fact, many regulated firms (literally all firms), regulations and how they work are a mystery and they have no idea how to comment effectively. It is important that people concerned with regulations know what to look for and how to comment effectively.

The process of regulating is governed by the 1946 Administrative Procedures Act (APA) which, as part of democratic government, requires agencies to solicit comments and respond to all significant comments.[2] In general, comments on regulations may either be submitted electronically or in writing. Regulations are designed to interpret laws[3] and may do so by further defining statutory terms, establishing a process to comply with the law, or establishing a

[1] A comment on a proposed federal rule, which is called a regulation when it is completed, is a written submission to the agency that is trying to put the rule forward that discusses any aspect of the proposed rule. It may be mailed to the agency or submitted as an email. At the end of each rule, the agency designates an individual with an address to which comments are directed.

[2] In cases where there are many comments that are the same, the agency may respond to them as a group rather than address them individually.

[3] Laws that direct regulatory agencies are passed by Congress and signed by the president. They tell the agency what they either can or must do in a regulation. Some are very specific and some are vague, leaving more discretion to the agency in the latter case.

standard. They have the force and effect of law and, in fact, many of the issues discussed in this paper might arise as a result of the original law. Agencies are bound by those laws and, if the issue is with the law itself, it may be more appropriate to appeal to Congress than to the agency.[4]

There is a concern by some that regulation controls a large part of our lives and yet is carried out by unelected bureaucrats.[5] Although executive branch agencies are under the direct control of the president and can be monitored by Congress, it is true that they have a great deal of autonomy. This is particularly so as so many regulations require the work of experts to accomplish them. This makes it all the more important that citizens insist that their regulations be intelligible and easy to comment upon.

One of the most common ways that agencies create regulations is through "informal rulemaking." In this type of rulemaking, agencies will usually publish a proposed rule (Notice of Proposed Rulemaking or NPRM) in the *Federal Register* that contains both a "codified" part of the regulation (the actual rules that, when finalized, will appear in the Code of Federal Regulations) and a "preamble," which has a discussion of why and how the agency thinks the rules will accomplish the goal of the regulation. It will also solicit information and discuss the rules it proposes to codify.[6] In addition, in proposed rules there will be a cost-benefit analysis (Preliminary Regulatory Impact Analysis) of the rules (particularly for economically significant regulations), which is required by executive order (from the president), and an Initial Regulatory

[4] People often will write or visit their congressional representatives to make their views known on a regulation.
[5] It was felt that the reason Congress needed to delegate such broad powers to regulate virtually all portions of the economy was that there were so many complex areas that Congress simply did not have the time or expertise to handle them.
[6] The APA "affords all interested persons an adequate opportunity to provide data, views, and arguments with respect to the agency's proposals and any alternative proposals of other interested persons." To afford all interested persons an adequate opportunity to provide data, views, and arguments with respect to the agency's proposals and any alternative proposals of other interested persons.

Flexibility Analysis (IRFA), which is an analysis of how the regulation will affect small businesses or other small entities. [7]

Before putting out a proposed rule, the agency may publish an Advanced Notice of Proposed Rulemaking (ANPRM) in the *Federal Register*, or it may meet with various constituencies to solicit comments on how the rule should be crafted. An ANPRM is generally published when the agency needs much more information before it chooses a course of action. For either an ANPRM or NPRM, once they have been published in the *Federal Register*, anyone may send the agency a written or electronic comment. A time limit for the acceptance of comments is specified in the proposal.[8] To find these regulations and comment, there is a clearinghouse for regulations at the multi-agency Web site called Regulations.gov. Regulations.gov is a part of what has been termed "e-rulemaking" that lists rules, ways to comment and, eventually, will have a "docket" with all other comments on those rules. There are ways in which people can be notified about recently published regulations using Regulations.gov.[9] The final rule is also published in the *Federal Register*, where the agency sets the date by which the regulated community must comply with the rule. The *Federal Register* is available online at http://www.gpoaccess.gov/fr/index.html. There is a good description of this process at Reginfo.gov.

[7] Other analyses that may be contained in regulations include a Paperwork Reduction Act (PRA) analysis or analyses or rules affect regulations include complying with the Unfunded Mandates Reform Act, the National Technology Transfer and Reform Act, the Data Quality Act, the Congressional Review Act, the Government Performance Results Act, or Executive Orders on Federalism (13132), Civil Justice (1298), Family Considerations (12606)

[8] The timeline is normally between 30 and 120 days. Agencies are often petitioned to extend the deadline for comments on large or complex rules.

[9] For example, anyone may sign up for an "RSS feed" (Really Simple Syndication) which is a Web feed that may provide summaries as well as links to the documents. To use this, you must install one of the many RSS readers on your computer and then select from one of the many established RSS feeds on Regulations.gov. The RSS feeds currently on Regulations.gov list all of the agencies who might issue regulations.

The *Federal Register* is not the only place that people read about regulations. In some cases, there are newspaper articles, and many businesses become alerted to upcoming regulations through trade journals. However, to comment effectively on regulations, it is always useful to go to the original source published in the *Federal Register*.

There is nothing inherently good or bad about regulations as a class just as might be said of the laws that underlie them. But not all regulations are necessary and, even when they are, it is possible to write them in such a way that they are not as helpful as they might be. An analogy to regulations that reduce risk might be chemicals that are put into the community pool to control the spread of illness. If you don't put in enough chemicals, they will not be effective. If you put too much, the pool will be an unpleasant place to swim. If you put the wrong kinds of chemicals, you may cause other illnesses. Most people trust that there is an expert who knows precisely the right kind and amount of chemicals but in reality, it is probably the 17-year-old lifeguard hired for the summer. Regulatory professionals do have knowledgeable experts in charge but because of the pressures exerted on them by various constituencies, including media, they may over or under reduce risk through regulation.[ii]

Although regulations are continually being modified, for the most part, once they are in place, they tend to stay in place as there is no real demand by any group to remove old, outdated, or unworkable regulations, even thought there are rules that are suppose to make that happen.[iii] Therefore, it is important that many different voices are heard in comments to proposed regulations.

There are numerous people in the federal government who review rules and may be impacted by comments. For example, a rule being written in the Food Safety and Inspection Service (FSIS)

of USDA will: 1) be written by a program office; 2) will then be reviewed by managers higher up in FSIS; 3) will be reviewed by the Office of General Counsel, and the Office or Risk Assessment and Benefit-Cost Analysis (the latter if it is a health or safety rule); 4) reviewed by senior managers in the Office of the Secretary of USDA; 5) reviewed by a desk officer and an economist in the Office of Information and Regulatory Affairs in the Office of Management and Budget; 6) reviewed by an advocate at the Office of Advocacy in the Small Business Administration and; 7) possibly, reviewed by other senior White House officials all the way up to the president. Decisions may change at any point in this chain, either through direct authority (The president is the ultimate authority) or by suggestions for change. That is just the executive branch. It is also possible that the regulation may be the subject of hearings by Congress or reviewed by the courts.

Participation in Rulemaking

Even before creation of the APA in 1946, there was concern about ensuring that rules were produced as democratically as possible. Legislators, sometimes for different reasons, have altered or added to the rules that govern the creation of regulations to try and ensure as broad and as deep participation as possible. In order for a person or organization to successfully participate in rulemaking, they must: 1) know about a rules existence, particularly at the proposal or pre-proposal stage; 2) have access to all supporting documents and meetings; 3) be able to understand the rule, the supporting analysis of the rule and how it is likely to affect them; 4) have the right to lobby the agency or Congress to affect the rule; 5) be able to do all of these things at sufficiently low cost to make it worthwhile to do so; and finally, 6) have some possibility of actually affecting a rule in their favor.

For rulemaking to work for all stakeholders, they must:

1. Know about a rules existence, particularly at the proposal or pre-proposal stage. The Unified Agenda and Regulations.gov are two government innovations that try to alert people to rules that are forthcoming or rules that have recently been proposed.[iv] In addition, there are requirements in the Small Business Regulatory Enforcement and Fairness Act (SBREFA) that requires OSHA and EPA to contact small businesses and solicit input from them. Privately, larger organizations either have staff devoted to tracking regulations or use third party suppliers for regulatory information. These third party suppliers focus either on industries (like trade organizations) or agencies, like Inside EPA or Food Chemical News. Traditional media, on the other hand, has historically only reported on rules that are large or controversial. In part because of the low media interest, following upcoming regulations is too costly for most individuals and very small firms. Although there were multiple outreach experiments in the 1970s, this situation still largely persists.[v]

2. Have access to all supporting documents and meetings. The Freedom of Information Act (FOIA) of 1966 ensures that individuals have access to U.S. government records and places the burden on the government to prove that records should not be released. A FOIA request must be written however and there may be fees for supplying documents. Further, it may take some time to grant a FOIA request. However, documents that an agency has relied upon to make a regulatory finding must be available in the agencies' "Docket." In some cases, dockets are posted electronically but in others individuals must go to the agency to request supporting documentation. In addition, the Federal Advisory

Committee Act of 1972 (FACA) requires that advisory committees are objective and accessible to the public. The Government in the Sunshine Act of 1976 required that agency meetings were open to public observation although there are many exemptions.[vi]

3. Be able to understand the rule, the supporting analysis of the rule and how it is likely to affect them. Rules have become both longer and more complex, particularly in the area of social regulations that are often supported by highly technical economic and risk analyses. In addition, preambles contain legal and scientific defenses that are sometimes written in highly technical language. In 1998, President Clinton issued the memorandum on Plain Language in Government Writing to help combat this.[vii] But trying to understand rules, their salience for particular groups, and particularly, what might be wrong with them remains a technically complex enterprise beyond many stakeholders. This paper takes one small step to help with this problem.

4. Have the right to lobby the agencies or Congress to affect the rule. This right has always existed although it was formalized by the Administrative Procedures Act of 1946. Even as far back as the 1930s, there were multiple ways to interact with agencies, including "oral or written communication and consultation; investigations, specially summoned conferences; advisory committees and hearings."[viii] In the 1970s, many statutes required hearings with the public including the Occupational Safety and Health Act and the Consumer Product Safety Act. Although it may not have been the intention at the time, the creation of the Office of Information and Regulatory Affairs (OIRA) in OMB on April 21, 1981 offers an alternative place in the executive branch, outside of the originating agency, for stakeholders to express their concerns.

5. Be able to do all of these things at sufficiently low cost to make it worthwhile to do so. One rule that helps to lower costs for participation is giving participants more time to comments on rules, notably going from 30 to 60 days. For example, the 1977 amendment to the Clean Water Act required that the Agency give 60 days for comment. Another means that the federal government has made to help lower costs is electronic submission of comments on Regulations.gov.

6. Have some possibility of actually affecting a rule in their favor. One method of ensuring that affected stakeholders have a real possibility of affecting the outcome of a rule is when they are promulgated by a little used addendum to the APA known as regulatory negotiation or "reg neg." These mechanisms are the outcome of the Negotiated Rulemaking Act of 1990 and allow for direct participation in crafting a rule. For normal rulemaking, there are multiple ways to try and influence rules: through Congressional representatives prior to, during or after rulemaking, through meetings with OIRA, meetings with the agency itself, by serving on advisory panels, through written or oral comments during public hearings or, if necessary through the courts. One thing that should be pointed out is that agencies may spend years developing a proposal and have considered a great deal of input prior to the proposal appearing in the *Federal Register* and this area is not directly governed by the APA.[ix] This is not to say that the notice and comment period is not effective and, in fact, "over the past several decades the courts have encouraged the bureaucracy to be more responsive to those groups and individuals who voice their opinions during rulemaking."[x]

In every one of these categories, Congress or the executive branch has tried to make is possible for stakeholders to successfully participate in rulemakings.

Does Participation Work?

Despite all of these innovations, successful participation is not yet where it needs to be for rulemaking to be truly democratic. The procedural rules discussed above may be viewed as trying to overcome the political problems inherent in any government action. Overcoming the problems associated with a monopoly provider of a service (government regulation) with vested interests to respond to votes, money, or philosophical compatibility is always going to be extremely difficult. This will be particularly true for those that agencies view as powerless, particularly because "The Administrative Procedures Act is silent with respect to instructing agencies what to do with the comments they receive."[xi] Although they tend to ignore some, agencies do pay attention to larger, more organized groups.[xii] Agencies will be somewhat responsive to interest groups, and Kerwin finds that over 80 percent of interest groups surveyed believe they have influenced rulemaking over half the time they comment and half of those are influential over 75 percent of the times they comment.[xiii] As to why they pay attention, one author suggests that bureaucracies pay attention to interest groups that either provide new data or help protect them against future legal challenges.[xiv] Although past models of influence over regulatory agencies suggests permanent capture (iron triangles consisting of Congress, the bureaucracies, and interest groups) by organized interest groups, more modern theory suggests that influence is exerted by shifting groups who exert influence over "issues of interest."[xv] That is, participation is characterized by "issue networks" that "are shared knowledge groups that tie together large numbers of participants with common technical expertise."[xvi] As a percentage,

business groups are the most frequent commenters on rules. The reason that advocacy groups do not submit as many comments may be because the agencies that they are interested in tend to accept advice from those who agree with their position.[xvii10] For example, environmental groups interests tend to neatly coincide with the interests of the bureaucrats in EPA.[xviii]

In sum, for those groups who are successful in influencing agencies, it is likely that they have more concentrated benefits, more resources, or tend to agree with bureaucratic preferences. For the others, there is a clear absence of "actual citizen participation" in rulemaking.[xix] The others in this case are likely to be citizens who are not part of activists groups and small businesses.

Armed with better information that can lower the cost of understanding and commenting on regulations, those currently left out may increase participation rates.[11] With most of the 115 million households in the United States having access to the Web through the internet and virtually all small businesses having access, there are issue networks that may be virtually formed to come together and exert influence that has previously been missing. So far, however, research has not demonstrated that this rulemaking revolution has occurred.[xx] This does not mean that more does not need to be done to produce more understandable regulations, better analysis on who is affected and how, and more pressure placed on agencies to defend why they have rejected individual comments. In particular, more pressure should be placed on agencies to defend dismissal of comments that disagree with proposed positions, particularly if those groups were not part of the pre-proposal stage of rulemaking. The following section is intended to help

[10] Also, advocacy groups are outnumbered by the sheer total of businesses.

[11] There are companies that specialize in helping firms comply with rules and that also may help comment. There are also currently many Web sources for information such as the free press (http://www.freepress.net/).

such newly formed interest groups who do not necessarily have access to a staff of regulatory experts who are adept at finding problems in regulations.

Issues with Regulations

The following is a list that describes both signals that something might be wrong with a regulation and many of the common problems with regulations that may be the subject of a comment.

A. Signals

These are not problems with regulations per se but are evidence that a deeper look is warranted.

A.1. The regulation is designed to help some at the expense of others. The regulation may end up helping society overall but the motivation for the regulation, if it can be discerned, should make you suspicious. Firms and industries have used regulations since the beginning to raise rival's costs. The two groups of firms that are normally adversely affected are those that are either not using a particular technology when a technology is mandated by the government or small firms who must bear large, fixed costs over a smaller sales base. This problem is compounded when there is a "bootlegger and Baptist" problem where advocacy groups and a sector of industry agree on the need for regulation to suit their own purposes.[xxi]

A.2. There is a problem that is heavily reported in the news and the regulatory agency is pressed to come up with a solution. When in this situation, regulatory agencies may be forced to appear

to be addressing the problem, even when they don't have a solution. It should not necessarily be presumed to be a bad regulation, just that it is less likely to be a good one.

A.3. The regulations are passed in the "midnight period" between (presidential) election results with a new incoming president and inauguration with little review, stakeholder consent, or accountability by the executive branch.[xxii] Studies have shown that more regulations, and particularly more economically significant regulations, have been passed during this period. There have been many reasons offered for this phenomenon, such as trying to embarrass the next administration, trying to fill out resumes before leaving administrative posts, or perhaps trying to get politically explosive rules through that earlier would have caused problems for the incumbent administration. No matter what the reason, stakeholders should view rules passed in this period with some suspicion.

A.4. The data presented has not been adequately peer reviewed. It may be that the data is not in compliance with the Information Quality Act and it may use poor or biased data.[xxiii] The Information Quality Act (also known as the Data Quality Act) aims to ensure the "quality, objectivity, utility, and integrity" of information that agencies either disseminate or use in rulemaking. It provides a vehicle for stakeholders to request corrections and improvements to data where it falls short of meeting these goals (although responses to these requests are not judicially reviewable). A plain understanding of this act is that it attempts to keep "junk science" out of rulemaking. Stakeholders should carefully examine the science that agencies use to determine whether it is credible. Publication in a peer-reviewed journal is one way this can be accomplished or the agency may put together its own peer-review process.

A.5. The agency relies heavily on inside experts for data. It is not unusual to have to rely on expert opinion used as data inputs for analyses. All such inputs should be documented with names of individuals attached to them. If all of the experts relied on work for the agency, dig deeper. Reliance on expert opinion should be robustly supported and the best way to do this is with multiple outside experts.[xxiv]

A.6. It is clear that an agency does not understand the industry or industries it is regulating. There will often be a discussion of industry practices either in the main part of the preamble to a rule or in the regulatory impact analysis that describes the baseline against which the regulation will induce changes. An example of this was an FDA regulation of smoked fish for botulism that required cooking to such an extent that the product was inedible.[xxv]

Issues with Regulations

The next several sections contain issues that that any potential commenter should be aware of when looking to comment on a regulation. In general, they fall into three categories: process, analysis, and outcome. If an agency has failed to write a regulation using an appropriate process, such as is outlined in the Administrative Procedures Act and other laws, that can be an issue for courts or oversight groups such as OMB or Congress. Since the first comprehensive executive order on economic analysis passed by President Carter (Executive Order 12044), the requirements for analysis have expanded rapidly.[xxvi] Finally, the outcome of the regulation, what the rule actually requires, and more importantly, how markets respond to those requirements, is what actually affects Americans. Interestingly, if the agency has followed the correct process and done all of the analysis correctly (and given only pro forma responses to the commenters and ignored the results of its own analysis), there is usually no remedy by the courts, changes are

likely to come only from those that oversee regulatory agencies.[xxvii] In short, the courts will only concern themselves if the agency has violated a statute like the APA, a procedural statute like the Paperwork Reduction Act, or the agency's organic statute. Violation of executive orders or "good" policy are not judicially reviewable unless litigants can show that the agency has been arbitrary and capricious.

B. Need for Regulation

There is a strong incentive for regulatory agencies to regulate, after all, that is the business they are in and their measures of success for some has been more or larger regulations. However, there is not always a need for regulation and when there is not, the likelihood is that there will be net social harms.

B.1. There is no problem to be solved. The bar for regulations in administrative law is fairly low and agencies are given deference in how they interpret statutes.[xxviii] In some cases, evidence for the need for a regulation can come from anecdotal evidence of problems that are not necessarily recurring. But regulations generally stay fixed in place forever and should only be used to fix systemic problems, problems that are expected to occur forever without a regulation. (Note: The bar is higher for an economic benefit analysis.[xxix])

B.2. The agency has not seriously considered issues of federalism, a basic division of governmental responsibilities established by the Constitution.[xxx] In addition to the constitutional question, states or localities with more local knowledge and more targeted regulations may be the appropriate place to address problems.[xxxi] In this case, there is no need for *federal* regulation.

B.3. The market will fix itself. The baseline for regulations should be one that projects what would happen without the regulation. If the market is already moving in the right direction, and the incentives to continue to do so are strong, no regulation is needed. Note that this implies both low (or no) costs and low benefits if a regulation is passed.[xxxii]

B.4 The regulation does not take into account other regulations that address the same problem, thus solving the problem more than once (at least analytically).[xxxiii]

B.5. The risk is insignificant. This is somewhat related to an issue where there is no problem to be fixed but in this case, there can be a small yet persistent risks that is simply not worth fixing by federal regulation. In legal language, this concept is known as *de minimis non curat lex* (the law takes no account of trifles). Unfortunately, as bureaucracies do not wish to close up shop, they must find more and more risks to regulate, even if they are small.[xxxiv]

C. Compliance with Law

All regulations are authorized by statutes passed by the Congress and regulatory agencies may not go beyond their statutory authority. This paper is not intended to provide legal advice and it is strongly suggested that if you suspect one of these problems may be an issue with the regulation you are addressing, you should contact an attorney who specializes in regulatory law.

C.1. The regulation goes outside of the agency's mission. In many cases, the agency will push or extend their legislative authority well beyond the intent of Congress. This is one reason that regulations are overturned in courts.[xxxv]

C.2. Supporting documentation is not found in the dockets management branch. Agencies are required to post all supporting documentation in the administrative record and this information should be available in their dockets management. If information is not present that the agency used to support the rule, this may be grounds for a court to remand the rule back to the agency.

C.3. The regulation is unconstitutional.

C.4.The rule is not well legally grounded. The Administrative Procedures Act requires that, "in order to set aside agency action, the court must conclude that the regulation is 'arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law.'" [xxxvi] The rule may also be judged to be an "abuse of discretion."

C.5. In a final rule, the agency did not give an adequate response to a unique comment. This may cause a court to set aside the rule.

C.6. The final rule was not a "logical outgrowth" of the proposed rule. The final rule does not need to mirror the proposed rule but there must have been some notice of each issue in the final rule given in the proposed rule. If there is not, an agency may be forced to re-propose all or a part of the rule.

C.7. The agency had private, *ex parte,* contacts with outside parties during the course of the rulemaking and did not publicly reveal those contacts.[12]

[12] Ex parte communications during the rulemaking process can give rise to three principal types of concerns. First, decision makers may be influenced by communications made privately, thus creating a situation seemingly at odds with the widespread demand for open government; second, significant information may be unavailable to reviewing courts; and third, interested persons may be unable to reply effectively to information, proposals, or arguments presented in an ex parte communication. In the context of section 553 rulemaking, the first two problems can be alleviated by placing written communications addressed to a rule proposal in a public file, and by

D. Stakeholders

Although there are few legal requirements, agencies should engage with stakeholders in an even-handed, transparent manner at every step of the regulatory process to both explain what they are doing and to receive stakeholder input on analysis and decisions.

D.1. The regulation is badly written, in legalese, or just unclear. This makes it extremely difficult for commenters to weigh in and constitutes an absence of transparency. In fact, agencies are required by a Presidential Memorandum to write in "Plain Language."[xxxvii]

D.2. Related to the previous point, analysis is presented using technical jargon or obtuse analytical results that only specialists can understand. Generally, this may be scientific language that is not explained, including economic and risk analysis or legal language.

D.3. The regulatory agency ignored the comments to a proposal in a final rule or did not adequately address them (this may be grounds for a legal complaint. One trick is to cite a large group of comments that disagree with the agencies position as "some commenters said . . ." even when the position represents the vast majority of comments.[xxxviii]

D.4. There is very little or no evidence that stakeholders have been engaged in a meaningful way by the agency for significant regulations. If, for example, a docket shows that a particularly

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disclosure of significant oral communications by means of summaries or other appropriate techniques. The very nature of such rulemaking, however, precludes any simple solution to the third difficulty. The opportunity of interested persons to reply could be fully secured only by converting rulemaking proceedings into a species of adjudication in which such persons were identified, as parties, and entitled to be, at least constructively, present when all information and arguments are assembled in a record. In general rulemaking, where there may be thousands of interested persons and where the issues tend to be broad questions of policy with respect to which illumination may come from a vast variety of sources not specifically identifiable, the constraints appropriate for adjudication are neither practicable nor desirable to afford all interested persons an adequate opportunity to provide data, views, and arguments with respect to the agency's proposals and any alternative proposals of other interested persons. http://www.law.fsu.edu/library/admin/acus/305773.html

affected subgroup has not commented on a regulation, while there may or may not be a legal obligation for the agency to seek out comment from a group in particular, it is good government for them to have done so.

D.5. The agency has failed to make its regulation or comments to a regulation available in an electronic form, or parts of the regulation or comments are difficult to find (again, an incomplete docket may be grounds for a legal complaint).

D.6. The agency fails to report costs in terms easily understood by stakeholders or useful for them. For example, expected costs per firm (and variability of those costs) may be more useful than total industry costs.

D.7. The agency has failed to provide sufficient time for comment based on the length and complexity of the rule. Although agencies are tending toward more time (e.g., 60 rather than 30 days to comment), it is important to request more time if the rule is extremely long or complex. This is also a problem for reviewers within the federal government during periods of "midnight regulations" or when there are other deadlines.[xxxix]

D.8. The agency, in this case EPA or OSHA, has failed to hold the required meetings required by the Small Business Regulatory Enforcement and Fairness Act of 1996 for small entities, including small businesses.[xl]

E. Economic Analysis

There are different types of analyses that agencies are required to do as part of both proposals and final rules. Perhaps most significantly, there is an executive order that requires both a

benefit-cost analysis and a cost-effectiveness analysis. Currently, there is guidance on how to do economic analysis in Circular A-4 from OMB).[xli] *There is also a statutory requirement to analyze the effects of regulations on small entities, including small businesses.*

E.1. The agency does not acknowledge the uncertainty of its findings and, even where it does so, does not evaluate how making alternative assumptions would change the outcome of their analysis. This may also be manifested as false precision. Uncertainty is always present in analyses including scientific findings, risk assessment, and benefit-cost analysis.[xlii]

E.2. The agency fails to identify (and quantify if possible) separate costs of a regulation. One prime candidate for this is the cost to firms of management oversight of regulations. Comments from some firms show that they do not always understand this as these are not accounting costs, they are the opportunity costs of management time.[13] Costs to government in administering regulations should also be included. Loss of liberty is another cost that agencies may leave out.[xliii] Unlike many other types of costs, attenuation of liberty may become more problematical as the rules build up. This cost has generally not been addressed in regulatory impact analyses.

E.3. The agency has failed to analyze a sufficient number or variety of options. Even when agencies do manage to evaluate a sufficient number of options, they often evaluate a few options that are nonsensical or not much of a deviation from their preferred alternative. Although they may not regulate outside of their statutory authority, they should analyze options outside of their statutory authority.[xliv]

[13] Opportunity costs are the costs of allocating resources (labor and capital) away from one use to another use. So even though management would be present and there is no increase in the costs of management time (accounting) due to complying with a regulation, there is an opportunity cost as management must stop working on other matters, e.g., firm organization, looking for new business opportunities, and focus on how the firm should comply with the rule.

E.4. While some parts of the regulation may be well supported, others are not. From an economic point of view, if parts of the regulation have costs exceeding benefits, even if the overall regulation has benefits exceeding costs, then those weakly supported parts should be eliminated—unless there are other reasons (outside of benefits and costs) to keep them. In many cases, agencies will cover more firms than necessary just to "cover all of the bases" and justify it as applying a "level playing field," but, in fact, it has the effect of making firms and consumers pay more for products that don't have problems.[xlv]

E.5. The regulation extends "benefits transfer" or other types of science from one rule or study in a different context to the present one inappropriately.[xlvi] This may also be done inappropriately for costs if cost estimates are used for a model plant or another industry inappropriately.

E.6. The regulation will severely inhibit technological growth and innovation without explicitly acknowledging this and carefully examining the trade-offs. Regulation can divert resources used for growth and innovation to other things, or it may add constraints in the form or type of innovations that are acceptable. It should be pointed out that regulation may actually help growth and innovation if consumer acceptance is seen as a problem and regulation is recognized as a solution for this problem (unfortunately, this is only theoretical; there is no evidence to date that regulation helps with consumer acceptance).[xlvii]

E.7. The regulation creates barriers to entry or other domestic or international trade problems without explicitly analyzing those barriers. The regulation fails to analyze these problems.[xlviii]

E.8. The regulation fails to consider the option of gathering more information to make a better-informed decision.[xlix] Options agencies should consider when there is a lot of uncertainty,

particularly as to the evidence of a problem or how to solve that problem include more research or pilot programs.

E.9. The agency over interprets, selectively interprets, or misinterprets scientific research, including professional articles, surveys, focus groups, and experimental studies.[l] Agencies face conflicting pressures which may cause them to use science in an inappropriate way to support what they wish to do.

E.10. The agency uses poorly researched (junk) science.[li]

E.11. Assumptions are hidden or why particular assumptions were chosen is not explained.[lii]

E.12. There is a loss of personal liberty that the agency has neither discussed nor analyzed.[liii]

E.13. The agency claims benefits from a regulatory action but there are no costs associated with that action. All benefits and costs stem from changes in the market (changed behavior, technology, etc.) and stem from the requirement to do something different than is done now. As such, there are always opportunity costs that result from the mandated or voluntary change in behavior.[liv]

E.14. The agency has failed to utilize one or more discount rates required by OIRA or has used a rate without sufficient explanation.[lv]

E.15. The agency has failed to identify all of the parties affected by the rule.

E.16. The agency has failed to identify the distribution of costs and benefits between different parties.

E.17. The agency has associated benefits and costs with legal requirements, as opposed to changed behavior. All benefits and costs result from changes in behavior, not legal requirements. This is a subtle point; legal requirements change how firms and consumers behave, although not always in the way intended. For example, the cost of a label requirement that puts a warning on food may be that the food is no longer made if the label is onerous enough to scare away consumers. The benefit would be the reduced risk from no longer consuming the food.[lvi]

E.18. The agency has inappropriately counted transfers as costs or benefits. Transfers are a transfer of resources from one group to another, e.g., profit transfers that do not affect resources.[14]

E.19. The agency has double counted benefits. For example, a regulation that reduces lead consumption may improve I.Q. scores. This in turn would lead to increases in productivity, but to count both would be double counting benefits.

E.20. The agency claims that the regulation will protect consumers in some fashion but there is no data to support the claim. In many cases, what constitutes consumer benefits may be obvious. However, the presumption ought to be that the benefits for consumers will actually obtain by inferring the value consumers place from trades they make in the market (e.g., buying safer cars) or by directly eliciting values. [lvii]

E.21. The agency has failed to note that an administrative threshold has been crossed—thresholds exist for the economic executive order (currently E.O. 12866), the Unfunded

[14] For regulatory flexibility analyses, economists will count estimate loss of profits as a cost for small businesses. However, for regulatory impact analyses, profits are simply transfers from consumers to producers; they do not constitute a loss of real resources (labor and capital).

Mandates Reform Act, and the Regulatory Flexibility Act (amended by the Small Business Reform and Enforcement Act).

E.22. The agency analyzes only the costs and benefits of the activities required by the regulation, but not of the other changes that will come about because of the regulation (otherwise known as "indirect costs"). For example, the analysis of a regulation requiring more stringent checking of worker documentation that did not also consider the impact on the labor supply would be incomplete.[lviii]

E.23. Distributional information on the risks and benefits are revealed while distributional information on the costs is concealed.

E.24. Costs to Business

In many cases, the regulatory options and costs of the rule will be the areas that businesses will know most about and are most likely to be the group that comments. It is important that businesses comment because they have the most direct knowledge of what their expenditures are likely to be.

Cost Factor Chart

The factors below can be used for commenting on each proposed requirement in the codified section. In general, a comment about costs will carry more weight if it is a survey of all or a representative sample of affected firms.

Category	Explanation	Examples
1. What type of worker will have to do something different due to this regulation?	Divide workers into categories based on their wages and salaries. Include anyone you will need to hire because of the rule.	Managers, quality control workers, production-line workers, contractors, laboratory workers, secretaries
2. What will those workers have to do differently?	Using the requirements of the rule, explain the new duties each person will take on. If it is something they are already doing, you should not include it, even though it is a requirement of the rule. (There will be no benefits for this activity either if it is already being done). Remember that what workers will be doing will depend on how the firm chooses to respond to the	A manager may have to oversee implementation of the regulation; a quality-control worker may focus more on a safety activity rather a quality-control activity; a new production-line worker may be hired.

	proposed requirement	
3. How much time will the new activity take for each category of worker?	Estimate by day, week, month, or year how much time will be spent on the new activity and whether the new activity is a one-time event or is a repeated activity.	A lab worker must perform 2 new tests per week taking a total of 4 hours per week or 200 hours per year (plant closed 2 weeks each year) every year.
4. What are the average salaries (or wages) by group or person engaged in a new activity?	Estimate the full annual cost of labor (salary plus overhead) or hourly rate for each category of worker who must change activities.	Managers are paid $35,000 per year including overhead. Production workers get $19 per hour including overhead.
5. What new capital equipment or materials will you have to buy to comply with the regulation?	Estimate the actual cost of new capital equipment or materials that you will have to purchase (one time or annually) and any loss of equipment that can no longer be used. Include disposal costs or any other accelerated depreciation. Also include	Chemicals for new tests will cost $40 per test for each of the 4 tests per week. The depreciated value of an extruder that will no longer be able to be used is $7,500.

	additional costs for energy.	
6. What is the size of your firm?	Estimate the size of your firm either by number of employees or by annual sales. A range may be given.	Our firm has 200 full-time employees and 20 part-time employees. Annual sales are between $10 and $50 million.
7. What products do you make?	Describe the type of products that your firm makes that are covered by the potential regulation. Breaking down costs by product may be a useful way to comment.	Our firm makes 2 varieties of herbal supplements in 3 sizes each. We make 4 flavors of Larry's Ice Cream in 2 sizes each.
8. What are your average annual profits?	Do not report sensitive information but you may wish to provide an approximate annual amount that you can use to finance new requirements. Generally, these are only important for small firms for use in regulatory flexibility analyses. However, if firm closure	My firm makes between $20,000 and $50,000 per year.

	becomes an issue because of revenue streams, it may be an issue for all firms.	
9. Who owns your firm? How many plants do you have?	Explain whether or not you are a subsidiary of a larger firm. If so, it may disqualify you from being a small business (for purposes of analysis) unless the entire firm is small.	We are a solely owned firm with 2 plants.

F. Risk

For regulations that address health or safety risks, agencies will often have prepared a risk assessment. Although there are guidelines from OMB on how to do this, practices vary widely.[lix] *Risk assessments may take the form of a safety assessment, which is a conservative finding of a safe dose or emission, or they may take the form of an actual estimate of the risk the regulation addresses.*

F.1. The agency leaves out part of the science that argues against their case. In most risk assessments, particularly safety assessments that find a safe level or dose, studies that find no effect, even when rigorous, are thrown out and the results of only those studies that found positive results are averaged.[lx]

F.2. The agency fails to take into account risk/risk trade-offs.[lxi] Risk/risk trade-offs imply that certain actions may make society even worse off by raising risks that are not the target of the regulation.[15] For example, this may be due to a change in what consumers purchase or a change in how a good is produced. The presence of risk/risk trade-offs is one reason that risk assessments should not be conservative. Of course, some risks that are not addressed by the target risk may also be reduced and strengthen the case for the regulation. A related type of consideration, health/health analysis is slightly more controversial. Health/health regulations theorize that by reducing private incomes to comply with regulations, less money will be spent on private risk reduction. Estimates range from around $7.5 to $15 million in regulatory expenditures per life lost.[lxii]

F.3. The analysis makes conservative assumptions or utilizes conservative defaults that are not warranted. A conservative risk assessment makes assumptions that ensure that the risk is not underestimated or that the safety level ensures that absolutely no harm can be done. In both cases, it handcuffs risk managers by not informing them as to the true risks that they must weigh with other factors—such as costs or countervailing risks.

F.4. The agency is addressing a problem that should be low priority compared to other problems in its purview.[lxiii]

F.5. The analysis does not take into account baseline actions of market actors.

G. General Problems with Regulations

This section addresses general problems found in regulations.

[15] An example of a risk/risk trade-off is not chlorinating water because of cancer concerns giving rise to problems with microbial pathogens.

G.1. The regulation is overly precautious to avoid under-regulation without being concerned about over-regulation. Precaution may make sense if there are large, irreversible effects and the science is tremendously uncertain. However, costs should be considered even in these cases.

G.2 The regulation is vague about what it is trying to accomplish or exactly how it will accomplish it. Each regulation should have a goal or objective that is outcome oriented (something that people value like increased reading skills or reduced risk). There should also be a clear connection between the goal and an actual means of achieving that goal or objective. That means that the goal should be directly tied to compliance with the codified part of the regulation. These goals and means should be easy to understand and make logical sense. Even when a performance goal is established, it should address various ways that the goal can be accomplished.[lxiv]

G.3. Logic. This is difficult to define but a commenter should check basic deductive and inductive rules of logic and look for logic fallacies that may present themselves. Clearly, there should not be emotional appeals in regulations or appeals to authority other than Congress.

G.4. The regulation appears to ignore the findings from the regulatory impact analysis.[lxv] The regulatory impact analysis is supposed to inform Congress, the president, and stakeholders, but its primary use is to inform the executive branch decision maker.

G.5. The agency violates its own guidance in how it will approach problems or how it will analyze problems (primarily risk assessments and benefit-cost analysis). Many agencies publish their own guidance on their Web sites.

G.6. The agency uses inappropriate baselines for comparison, e.g, comparing gains made in air quality to eastern Europe as though, without the regulations, U.S. air would become that bad.[lxvi]

G.7. Unsubstantiated assertions are made in the regulation, i.e., statements made about consumer understanding or misunderstanding without supporting survey evidence. Often, agencies will cite anecdotes as evidence about a problem, practice, or level of knowledge and apply the information derived from the anecdotes to a population of firms or consumers inappropriately.

G.9. The regulation will not solve the problem it intends to address. In some cases, the agency fails to make the case that even theoretically the regulation can work; in other cases, there is insufficient evidence that the remedy will work.

G.10. The requirements in the codified section are vague and subject to arbitrary enforcement. The agency may claim that there are lower costs than would be the case if the rules were enforced on all members of an industry. This claim is made because the agency claims that provisions will be enforced at the discretion of the agency. Unless there is an accompanying explanation of exactly the conditions for enforcement, this is not a legitimate claim.[lxvii]

G.11. Costs exceed benefits.[lxviii] There should be some explanation of why a regulatory option was chosen in which costs of complying with that option exceed the benefits of it.

G.12. There is a better option than the one that is chosen.

G.13. Agencies claim to rely on states for enforcement of the regulations without explicitly determining whether states are willing and able to enforce them.

G.14. Related to the previous comment. There is an unfunded mandate—a requirement that falls on states or localities without funding for them to carry it out.[lxix] Sometimes regulations are designed to minimize the burden on both the federal and state governments by transferring the burden to businesses.

Effective Consumer Comments

The issues raised above are ones that are essentially technical criticisms of regulations. They may very well persuade those of a technical bent that the regulation is not legal, has costs exceeding benefits, is not likely to accomplish its intended purpose, or will cause more harm (e.g., risk) than good. However, many policymakers are affected by the same kinds of non-technical considerations that affect ordinary consumers and these have been the subject of many years of psychological study.[lxx] The question for many policy makers for a particular regulation may be, "Is it the right thing to do?" For example, if a risk regulation appears to protect a particularly vulnerable subpopulation, it is likely that the total cost may well be irrelevant for many people and policy makers.

One additional way to comment on regulations is to address the acceptability of the approach to regulating risk. The concerns that drive people in risk situations are things like the degree of control they believe they have over the risk, whether there is the potential for catastrophe, the distribution of benefits and costs, and who is perceived to be at the cause of a problem. Addressing these kinds of issues, in addition to those technical concerns listed above, may provide decision makers with helpful information.

As mentioned earlier, comments on regulations are likely to be more effective if they are part of an organized group, even if only organized around a particular issue. Small businesses in an industry, for example, may be particularly more salient for an agency if they present a unified comment. This is not to say that a well-reasoned comment will not be effective, but regulatory agencies are political entities and, as such, politics will always play a role.

Conclusion

Regulations continue to affect a larger part of our lives and, once on the books, are rarely removed. While improvements have been made to this process since passage of the Administrative Procedures Act in 1946, there are still many people who are affected but are left out of the development process, some by choice, some because they do not use their democratic right to participate effectively. Because the regulations are difficult to understand and because many of the left-out do not have access to technical regulatory experts, more help in this area may lead to issue coalitions to address this inequality. This paper makes a small generic step toward helping those potential coalitions.

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i. Testimony given by M. Elizabeth Magill, University of Virginia School of Law before the Senate Subcommittee on Commercial and Administrative Law, July 25 2006, Serial No. 109-133.

ii. Pressure may come from being captured as first discussed by Marver Bernstein in Regulating Business by Independent Commisson, in 1955. More generally, media pressure tends to also place pressure on Congress which may respond by writing letters to the agency or holding hearings to demand action on a particular regulation.

iii. There are various requirements for agencies to perform "retrospective review." However, the agencies have no incentives to remove existing regulations and firms view most of the costs as both "sunk" costs and potential barriers to new entrants.

iv. http://www.gpoaccess.gov/ua/index.html and http://www.regulations.gov/search/Regs/home.html#home

v. Kerwin, Cornelius, *Rulemaking, How Government Agencies Write Law and Make Policy*, CQ Press, Washington DC, 1999, p. 172.

vi. http://en.wikipedia.org/wiki/Government_in_the_Sunshine_Act

vii. http://www.plainlanguage.gov/whatisPL/govmandates/memo.cfm

viii. Kerwin, p. 160.

ix. Testimony given by William West, The Bush School of Government and Public Service, Texas A&M University before the Senate Subcommittee on Commercial and Administrative Law, July 25 2006, Serial No. 109-133.

x. Yackee, Susan Webb, "Sweet-Talking the Fourth Branch: The Influence of Interest Group Comments on Federal Agency Rulemaking, Journal of Public Administration Research and Theory, 16, p. 104.

xi Golden, Marissa Martino, "Interest Groups in the Rule-Making Process: Who Participates? Whose Voices Get Heard," *Journal of Public Administration Research and Theory*, 8(1998):2, p. 259.

xii. Kerwin, p. 184.

xiii. Kerwin, p. 200.

xiv. Yackee, 105

xv. Golden, pp. 245-70.

xvi. Golden, 249.and Heclo, Hugh, "Issue Networks and the Executive Establishment," In Anthony King ed. The New American Political System, Washington D.C. AEI, 1978.

xvii Golden, p 262.

xviii. Kerwin, p. 188 suggests that environmental interest groups need not engage in expensive lobbying. Golden, p. 253 finds in a small studies that comments are mostly by "corporations, public utilities or trade associations.

xix. Golden, p. 265.

xx Testimony of Cary Cognlianese, University of Pennsylvania law School before the Senate Subcommittee on Commercial and Administrative Law, July 25 2006, Serial No. 109-133.

xxi. Yandle, Bruce, "Bootleggers and Baptists: The Education of a Regulatory Economist," Regulation 7, no. 3 (1983).

xxii. Davies, Antony and Veronique de Rugy, "Midnight Regulations: An Update," Mercatus Center at George Mason University working paper and McLaughlin, P.A. "Empirical Tests for Midnight Regulations and Their Effect on OIRA Review Time," (January 5, 2009). Available at SSRN: http://ssrn.com/abstract=1340733

xxiii. http://www.whitehouse.gov/omb/inforeg_agency_info_quality_links/

xxiv. A good example of this is the benefit analysis of FDA's Seafood HACCP Final Regulation in 1995 which utilized two "experts" to predict that 50% of all seafood illnesses would be reduced as a result of the regulation. http://www.cfsan.fda.gov/~lrd/haccpria.htm

xxv. P. Michael Davidson, John Sofos and A.L. Branen, *Antimicrobials in Food*, CRC Press, Edition 3, 2005, p 21

xxvi. United States General Accounting Office, Victor Rezendes, "Federal Rulemaking: Procedural Requirements at OSHA and other Agencies," Testimony before the Committee on Education and the Workforce, House of Representatives, Thursday, June 14, 2001. http://www.gao.gov/new.items/d01852t.pdf

xxvii. Even here, however, Agencies are given some discretion. See Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council. http://en.wikipedia.org/wiki/Vermont_Yankee_Nuclear_Power_Corp._v._Natural_Resources_Defense_Council,_Inc.

xxviii. The main citation for deference afford an agency is t he Chevron, USA, Inc. v. NRDC decision. A discussion can be found at http://www.utcle.org/eLibrary/preview.php?asset_file_id=7 and at http://en.wikipedia.org/wiki/Chevron_U.S.A.,_Inc._v._Natural_Resources_Defense_Council,_Inc.

xxix. See, for example, OMB Circular A-4, September 17, 2003 pp 15-17. http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf

xxx. http://www.usconstitution.net/consttop_fedr.html

xxxi. http://www.epa.gov/fedrgstr/eo/eo13132.htm

xxxii. IBID., OMB Circular A-4.

xxxiii. This may be regulations that the agency has already passed, regulations that are being prepared simultaneously or regulations from other agencies. For the latter, it is the job of the

Office of Information and Regulatory Affairs to coordinate regulations between the different agencies.

xxxiv. There are many examples of regulating tiny risks in the government. See, for example, Tom Lorantger and Damon Delistraty, Over-and under-regulating Hazardous Waste, *Environmental Impact Assessment Review*, 19 (1) January 1999, pp 99-108

xxxv. The governing case on how well the agency has stayed within their mandate is known as "Chevron." A discussion of this case can be found at http://www.law.cornell.edu/supct/html/historics/USSC_CR_0467_0837_ZS.html.

xxxvi. http://en.wikipedia.org/wiki/Administrative_Procedure_Act#Standard_of_judicial_review)

xxxvii. President Clinton's Memorandum can be found at http://www.plainlanguage.gov/whatisPL/govmandates/memo.cfm.

xxxviii. An example of this can be found in FDA's Seafood HACCP rule. http://www.foodsafety.gov/~comm/haccpsea.html

xxxix. For the general deadlines program, see: http://www.mercatus.org/uploadedFiles/Mercatus/Publications/MOP51_OIRAweb.pdf. For the Midnight Regulations Problem see: http://www.mercatus.org/PublicationDetails.aspx?id=25654.

xl. http://www.sba.gov/advo/laws/sbrefa.html See Section 244 on Small Business Advocacy Review Panels.

xli. http://www.whitehousD.gov/omb/circulars/a004/a-4.pdf

xlii. A good paper on this is: Williams, Pamela R.D. and D. J. Paustenbach, "Risk Characterization: Principles and Practice," Journal of Toxicology and Environmental Health, Part B, (5), 2002, pp 359-65.

xliii. OMB Circular A-4 is a good introduction to cost theory. Also see the National Center for Environmental Economics Guidance, Chapter 8 http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/Guidelines.html/$file/Ch8.pdf.

xliv. OMB's Circular A-4 suggests multiple types of "alternative regulatory approaches" including different choices defined by the statute, different compliance dates, different enforcement methods, different degrees of stringency, different requirements for different size firms, different requirements for different geographic regions, performance standards rather than design standards, market-oriented approaches rather than direct controls, and informational measures rather than regulation.

xlv. Any good microeconomics or benefit-cost textbook will provide a useful discussion of "marginal" benefits and "marginal" costs. Essentially, the concept is that each separable aspect of a project should be evaluated on its own merits. So for example, if you are regulating two industries and the benefits of regulating one industry exceeds costs by $50 (net benefits = benefits-minus costs) and the other has costs exceeding benefits by $30, overall there would be

net benefits of regulating both industries of $20. But it doesn't make sense to regulate the second industry, not doing so increases net benefits from $20 to $50.

xlvi. For a discussion see: http://www.uea.ac.uk/env/cserge/pub/wp/gec/gec_2000_25.pdf.

xlvii. For a discussion of how to handle new technologies see Gary Marchant, "Lessons for New Technologies," Mercatus Working Paper, no. 08-26, August 2008. http://mercatus.org/uploadedFiles/Mercatus/Publications/WP0826_RSP_Lessons%20for%20New%20Technologies.pdf

xlviii. For a discussion of regulation and productivity see: Giuseppe Nicoletti and Stefano Scarpetta, "Regulation, Productivity and growth: OECD Evidence," *Economic Policy* 18 (36) Apr 2003, pp. 9-72.

xlix. One good summary article in the Value of Information literature is Fumie Yakota, and Kimberly M. Thompson, Value of Information Literature Analysis: A Review of Applications in health Risk Management," Medical Decision Making, 24(3) 2004 pp. 287-98.

l. There are probably many general papers that could be applicable to this but one interesting, if controversial book on this issue is Lawrence Solomon, *The Deniers: The World-Renowned Scientists Who Stood up against Global Warming Hysteria, Political Persecution and Fraud,* Richard Vigilante Books 2008.

li. The Data Quality Act is supposed to prevent this, for a complete discussion see Carlo Batini and Monica Scannapieco, *Data Quality, Concepts, Methodologies and Techniques, Springer 2006*.

lii. Revealing assumptions is good for any analysis, including benefit-cost analysis and risk assessment. Assumptions should not be designed to achieve a particular outcome, they should be based on likely conditions and should only be made by experts. Further, where there are areas where different assumptions will affect the outcomes, then there should be a sensitivity analysis so that all possible outcomes can be revealed.

liii. Loss of liberty is typically not a "cost" that is counted in regulations but clearly regulations have a huge impact on liberty, particularly in how entrepreneurs pursue their business. Loss of liberty has become more visible recently with many examples coming in the area of homeland security such as the security measures at airports.

liv. See Richard A. Williams and Kimberly M. Thompson, "Integrated Analysis: Combining Risk and Economic Assessments While Preserving the Separation of Powers," *Risk Analysis* 24(6) 2004, pp 1613-23.

lv. Circular A-4.

lvi. Williams and Thompson

lvii In FDA, a senior regulator once remarked to me that the reason FDA standardized the size of canned sliced pear halves was because, for it was important for people who give dinner parties

that the sizes of the pear halves not be too different because it could upset adjoining guests if their salad (pear halves, cottage cheese and a cherry) had a different size.

lviii. In some cases, costs that are incurred that are not the direct result of a requirement are called "indirect" costs. This is misleading as all costs are derived from changes in behavior as a result of new market conditions and, as such, all are indirect. See the above referenced Williams and Thompson.

lix. http://www.whitehousD.gov/omb/assets/regulatory_matters_pdf/m07-24.pdf

lx. An alternative is called a Weight-of-Evidence (WoE) approach. There is a short discussion of this in the National Research Council's *Science and Judgment in Risk Assessment*, National Academy Press, Washington D.C. 1994, pp 311-14.

lxi. See for example, Graham, John D. and Jonathan Wiener, *Risk vs. Risk: Tradeoffs in Protecting Health and the Environment*, Harvard University Press, Cambridge, 1995.

lxii. Two key papers on this include Hahn, Robert, R. Lutter and W. Kip Viscusi, "Do Federal Regulations Reduce Mortality," and Keeney, Ralph L., Mortality Risks Induced b the Costs of Regulations, 8 Journal of Risk and Uncertainty 95, 1994.

lxiii. For a good discussion of regulatory priorities, see Adam Finkel and Dominic Golding, *Worst Things First?: The Debate over Risk-Based national Environmental Priorities*, Resources for the Future, 1996.

lxiv. In addition to actually writing a performance goal, it is a good idea that the goal be linked to overall agency performance goals. For a good discussion of this see Jerry Brito and Jerry Ellig, "Toward a More Perfect Union: Regulatory Analysis and Performance Management, Mercatus Working paper, No. 08-12, May 2008. http://mercatus.org/uploadedFiles/Mercatus/Publications/PDF_Toward%20a%20More%20Perfect%20Union_Regulatory%20Analysis%20and%20Performance%20Management.pdf

lxv See Richard Williams, "The Influence of Regulatory Economists in Federal Health and Safety Agencies, Mercatus Working Paper 08-15, July 2008. http://mercatus.org/uploadedFiles/Mercatus/Publications/8-influence20080729_RSP_WP0815_Goveconomists-final.pdf

lxvi. See Circular A-4 for a good discussion on baselines.

lxvii. Agencies may try and underestimate costs by saying that they will rely on "agency discretion" when enforcing rules.

lxviii. In the current executive order, 12866, it says that costs should be "justified by benefits." http://www.whitehouse.gov/omb/inforeg/eo12866.pdf

lxix. See the Unfunded Mandates Reform Act of 1995. http://www.sba.gov/advo/laws/unfund.pdf

lxx. See, for example, Paul Slovic, "Perception of Risk" Science 236 (17) April 1987.