REGULATORY SUNSHINE

APPLICATION OF BEST AVAILABLE SCIENCE CONCEPT

AND

METRICS FOR EVALUATION OF SCIENTIFIC CLAIMS

TO

REGULATORY TRANSPARENCY

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INTRODUCTION

This report summarizes a number of scientific papers, books and reports written by us individually and collectively. It expresses our concern on how science is used in policy notably regulatory decisions and provides a potential process to judge the validity of various scientific claims.

For a number of reasons we consider transparency of scientific information used by government agencies to be not only desirable but critical for the acceptability of policy decisions. The "Regulatory Science Sunshine Act" proposed for the Environmental Protection Agency (EPA) is equally applicable not only to all other regulatory agencies but also fundamentally to all policy decisions. The proposed Regulatory Science Sunshine Act would require that regulatory agencies develop processes, procedures, and methods for each regulatory decision that is based on or includes science:

- Identification of assumption judgments, default data, or other similar systems used in the regulatory process, identification potential alternatives, and how the conclusion would be different if alternative assumptions, judgments, and similar parameters were used.
- Description of the content of all mathematical formulations in words.
- Ensuring that the scientific information used in regulatory decisions is written in a language that is understandable to a knowledgeable non specialist and the average person.
- Demonstrating clear and unambiguous justification for the inclusion of societal objectives in their scientific assessment.
- Complying with relevant ethical requirements.

The proposed Regulatory Science Sunshine Act would require that regulatory agencies make a concerted effort to develop relevant processes, procedures, and methods to respond to the needs identified above. A possible approach may be to follow the process used in the Emerson Amendment that mandated the Office of Management and Budget to develop a guide on peer review that all agencies were required to follow.

It is highly likely that there will be opposition to regulatory science sunshine, as occurred with the peer review requirements. The opposition to transparency in regulatory science is likely to be based on the following:

- The "average citizen" is not educated enough or in formed enough to appreciate the intricacies of science used in the regulatory process.
- There are those who consider the Regulatory Science Sunshine Act to be burdensome. They may claim scientists in regulatory agencies have a unique competency but others do not have relevant experience and competency to participate at the level of scientific principles.
- The identification of potential uncertainties would result in opposition of the public to the relevant regulation. It is being claimed that people would suggest that in view of these uncertainties no money should be spent to promulgate or comply with a specific regulation

- Some lobbyists with access to regulatory agencies prefer the current situation because they can impact the regulations without the remainder of the society having the ability to judge the scientific foundation of their decisions without significant efforts.
- Members of a variety of advocacy groups also prefer the current situation, as long as the political leadership is supporting them.
- There are numerous other individuals and groups who are either opposed to transparency or do not care one way or another.

Let us use the example of Hurricane Irene to demonstrate the point. Events related to this hurricane started at about August 15, 2011 and a few days later, it became clear that Irene would impact the U.S. The pathway of Irene was modified as the hurricane moved closer and its severity was modified several times from category I to category II and Category III, but as Irene landed it was largely category I. Many cities and communities had to make decisions based on the information they received at any given time and in every case the information was uncertain and incomplete until Irene landed. Should the decision makers wait until they had complete and fully reliable information? No responsible decision maker would do so. Conversely, often the predicted weather proves to be wrong. How often a sunny day is predicted and how often rain or snow is predicted but the predictions prove to be wrong. Obviously, those impacted by the prediction had to make decisions based on the scientific information with various level of uncertainty

The term *Best Available Science* (BAS) is frequently used by individuals and groups implying that they have tried to identify available scientific information and selected the best option among them. However, in certain cases the selection of scientific information based on the desire of those who make the selection to "cherry pick" the information that supports their preconceived notion. What is being overlooked is that the BAS concept and *Metrics for Evaluation of Scientific Claims* (MESC) are based on well-established scientific principles and processes. As shown in Appendix I, the BAS/MESC system consists of the following:

- Five primary Principles that constitute its foundation
- One Pillar that addresses the level of reliability of scientific information
- One Pillar that describes the level of maturity of scientific information
- One Pillar that addresses areas that are Outside the Purview of Science

One of the key aspects of scientific information used in regulatory decisions is that in almost every case, the science attempts to predict a future event and inherently contains uncertainties. For example, it tries to predict adverse consequences of exposure to mercury resulting from emissions from coal power plants. In the overwhelming majority of cases these predictions include assumptions, judgments, inclusion of default data, and numerous other items that cause a certain level of uncertainty. The BAS/MESC system does not suggest that regulators should make their decisions based on scientific information that excludes uncertainties. Instead, we are asking for scientific transparency or scientific sunshine, as we call it.

EVOLUTION OF REGULATORY SCIENCE

The regulated and a segment of the scientific community complain about the poor quality of scientific information used by many regulatory agencies, particularly those dealing with

environment, ecology (including endangered species), nutrition, drugs, and environmental health. The confirmation of these complaints is beyond the scope of this report. However, a description of the evolution of regulatory science may provide not only the reasons but also a potential solution for the problems leading to these complaints. Note that regulatory science is defined as a scientific discipline consisting of the development and application of scientific methods, tools, approaches, and other relevant processes derived from various scientific disciplines used in regulatory and other policy decisions or simply stated scientific information used in regulatory decisions. Historically the evolution of regulatory science took place in three phases as follows:

Initial Phase: This phase is characterized by lack of sufficient scientific information to promulgate regulations. The Food and Drug Administration (FDA) has a long history of operation in this phase which was reasonably completed sometimes in the 1970s or 1980s. In contrast, during the Initial Phase of the history of EPA and Fish and Wildlife Service, a process was used that can be described as the application of the Most Relevant Available Information (MRAI) consisting of using information that was determined to be the most relevant; ranging from peer-reviewed and credible scientific information to personal opinion of a credible individual.

Exploratory Phase: During this phase, an attempt was made to move SI used in regulatory decisions from the Initial Phase to a process that would be scientifically more acceptable. These included the development of scientific tools to improve MRAI including the development of risk assessment process and independent peer review

Standard Operational Phase: As the title implies this phase should apply tools developed during the Exploratory Phase to regulatory decisions. For example, the FDA has required the withdrawal of a number of drugs and has identified limitations of usefulness of other drugs. At the EPA, there are mandates in the Drinking Water Act and Clean Air Act to periodically review relevant standards. However, in the overwhelming majority of cases, the standards have remained unchanged or become more restrictive.

INDEPENDENT PEER REVIEW

Peer-review is one of the most important elements of acceptability of scientific claims. As described in Appendix II, key elements of independent peer review are as follows:

- Assessment of qualification of the reviewers
- Assessment of independence of the reviewers implying a lack of conflict of interest
- Review criteria (questions provided to the Review Panel)
- The role of the editor of the scientific journal and its equivalent in institutional peer review
- Transparency of the entire process

RELEVANT ETHICS

One of the key issues needing the consideration of legislators and regulators is compliance with ethical principles of regulatory science. These principles were only recently formulated but are readily derivable from ethical principles of virtually all professions notably science, engineering, and medical professions

Principle I:

A scientific issue is settled when anyone with the necessary scientific skills, required equipment, and facilities can reproduce it.

On more than one occasion proponents of an issue claim that "science has spoken" or "science is settled" or several other phrases indicating that the scientific part of a regulatory process has been clarified. In effect, those who make such a claim must provide evidence that the science is reproducible and falls into Proven or Reproducible Evolving scientific information.

Principle II:

Those who prepare a scientific assessment document for application in regulatory decisions must provide to the affected community assumptions, judgments, and similar parts in a language understandable to a knowledgeable non-specialist.

This principle includes the consequences of using "assumptions, judgments, and similar parts", the justification of using them, and potential alternatives that were not used. This principle is based on the Transparency Principle. The regulated community, the scientists and their organizations, and the interested members of the public are entitled to know that regulatory science is used in a specific decision.

Principle III:

Scientific information used in the regulatory process must exclude societal objectives thus violating the Pillar "Areas outside the Purview of Science".

During the initial phases of the EPA, the need for rapid promulgation of regulations led to "being protective" and included societal judgments in the scientific process. One can argue that during that period those actions were justified. However the Standard Operating Phase of regulatory science the inclusion of societal objectives in scientific information used in regulatory decisions must be justified.

Principle IV:

Scientific information used in the regulatory process is only then acceptable if it has been subjected to independent peer review and the review criteria (questions provided to peer reviewers) include compliance with ethical principles I, II, and III.

There is a consensus within the scientific community that peer review is a prerequisite for acceptability of scientific claims. However, the peer review of scientific information used in

regulatory process is particularly important because of the usage of assumptions, judgments, and similar parts. It is crucial to ensure that the selection of assumptions, judgments, and similar parts is not based on a preconceived desire to promote a specific goal.

CONCLUSIONS

Scientific information used in regulatory process inherently contains a certain level of uncertainty requiring assumptions, judgments, inclusion of default data and other processes. Based on legal mandates, political desires, ideology, and many other reasons the regulatory decision makers promulgate regulations. Currently, the regulators have no reasons for transparency. At best it can be argued they have a moral, ethical, and community obligation to provide the affected community and ultimately the pubic with their assumptions and judgments, justification for the inclusion of default data, conclusions derived from them, and conclusions that may be derived from reasonable alternative assumptions, judgments inclusion of default data. It is highly desirable for the Congress to mandate sunshine in the scientific information used in the regulatory process. The Regulatory Sunshine Act would require that scientific assessments used in the regulatory process identify assumptions, judgments, inclusion of default data and other relevant processes; potential alternatives; and conclusions derived from these alternatives. Similarly, information used in the regulatory process must be subjected to independent peer review and the review criteria (questions provided to the reviewers) must address issues dealing with transparency.

APPENDIX I

BEST AVAILABLE SCIENCE AND METRICS FOR EVALUATION OF SCIENTIFIC CLAIMS

Many laws, regulations and other policy documents use terms such as best available science, best available data, and most reliable data. However, in all cases, the decisions on what constitute the best or the most reliable is left up to the decision maker. However, as a general rule the decision makers are ultimately responsible for all aspects of their decisions. Recognizing the need for providing the decision makers, the affected community and ultimately the general public we developed the concept of Best Available Science (BAS) and Metrics for Evaluation of Evaluation of Scientific Claims (MESC) derived from the BAS.

Fundamental Principles

Open-Mindedness Principle: This principle implies that the regulatory science community and the general public must be willing to consider new knowledge and new scientific claims.

Skepticism Principle: This principle requires that it is incumbent upon those who make a scientific claim to provide sufficient evidence supporting their claim. The Skepticism Principle provides balance and ensures that the Open-Mindedness principle is not misused.

Universal Scientific Principles: The Universal Scientific Principles are a set of basic principles and standards that apply to virtually all of the scientific disciplines including regulatory sciences.

Transparency Principle: Those who make a scientific claim have not only the intellectual but also the ethical obligation to identify the level of maturity and reliability of each segment, and if societal or other areas outside the purview of science are included in the claim.

Reproducibility Principle: Reproducibility is the proof of validity of any scientific claim, and separates undisputed areas of science from those that include assumptions and interpretations.

Pillar: Classification of Scientific Information

It is well established that science evolves and that new discoveries, advancement of scientific knowledge, and numerous technologies result from the evolution of science. Therefore, it is necessary to classify scientific information in terms of its level of maturity and its reproducibility.

Class I: Proven Scientific Information: This class consists of scientific laws (or principles) and their application. The scientific foundation of information included in this class is understood and meets the requirements of the Reproducibility Principle. Scientific laws or principles provide predictable and reliable results. As the majority of SI used in the regulatory process seldom qualifies as Proven Scientific Information, further discussion is not required.

Class II: Evolving Scientific Information: The overwhelming majority of scientific advancements and virtually all scientific information used in the regulatory process are included in this class.

Reproducible Evolving Scientific Information: Reliable and reproducible information dealing with a subject that is not completely understood constitutes the core of this class. Much of medical science provides a good example of Reproducible Evolving Scientific Information. Like Class I (Proven Scientific Information) information in this class meets the Reproducibility Principle. However unlike Proven Scientific Information, the scientific foundation of information in this class is often either unknown or the knowledge is incomplete.

Partially Reproducible Scientific Information: Sometimes referred to as Rationalized Scientific Information or Scientific Extrapolation this class includes a large segment of scientific information used in the regulatory process including predictive models. Although it builds upon Proven or Reproducible Evolving Scientific Information, it uses assumptions, extrapolations, and default data to derive its results. An important characteristic of this class is its level of reproducibility. Whereas the scientific foundation of this class meets the Reproducibility Principle the choice of assumptions, mathematical processes, default data, and numerous other prerequisites are inherently arbitrary and thus are not necessarily reproducible.

Correlation-Based Scientific Information: This class attempts to correlate systematic observations performed in accordance with Universal Scientific Principles to an effect. There is an extensive literature covering this class including a large segment of epidemiology. As described by the so-called Hill criteria correlation does not necessarily imply causation and as expected, some correlations have correctly identified their cause but others have proven to be unrelated. A summary of Hill criteria is as follows:

- Temporality: The exposure must precede the effect.
- Strength: There must be a reasonably strong statistical association.
- Dose-response: The dose-effect relationship must be consistent with the observed association.
- Consistency: There must be repeated observations by different investigators, in different places, different circumstances, and different times.
- Coherence: Cause and effect relationship must be congruent with current knowledge of the natural history and the biology of the disease.

Hypothesized Scientific Information: An organized response to an observation, an idea, or any other initiating thought process constitutes the core of this class. This class seldom if ever has a scientific foundation. Obviously, this class does not comply with the Reproducibility Principle.

Scientific Information based on Judgment: In the absence of relevant SI, decision makers may seek advice from knowledgeable individuals, groups, or use their own judgment to make decisions. Regardless of the process used, the results are still tantamount to an educated guess.

Speculation: Speculation is based solely on the opinion and intuition. Often the objective of speculation is to initiate a research project or stimulate a scientific discussion.

Fallacious Information: Most unfortunately, the scientific community and the general public are often provided fallacious information presented as science. Often called "junk science" or "pseudo science," some of the information provided to the regulators by special interest groups qualifies as fallacious information.

Pillar: Reliability of Scientific Information

This Pillar requires a formal and generally acceptable process to categorize the reliability of SI. Consequently, SI is divided into several distinct categories in ascending level of reliability

Category I: Personal Opinions: Expression of views by individuals regardless of their training, experience, and social agenda are seldom reliable.

Category II: Gray Literature: Reports prepared by government agencies, advocacy groups, and others that have not been subjected to an independent peer review are included in this category. Gray Literature is often no more reliable that personal opinion.

Category III: Peer Reviewed Scientific Information: The acceptability of a scientific claim requires that it has been subjected to independent peer review and has passed the strict scrutiny by independent scientific peers. Peer review is a well established process and is used extensively in scientific publications and grant submission. Briefly, an acceptable peer reviewer is an individual who is capable of understanding and performing the project under review with little or no additional study. Furthermore, the reviewer must also be independent and without conflict of interest. Finally, those who have a stake in the outcome of the review may not act as reviewers or participate in the selection of the reviewers. Despite its acknowledged shortcomings peer review is the only available mechanism to assess the validity of a scientific claim, aside from reproducing the actual claim.

Category IV: Consensus-Processed Scientific Information: In the consensus process an expert panel, convened in a manner similar to that described for Review Panels, evaluates the proposed information. Since much of regulatory science falls into the Rationalized, Correlation-Based, or Hypothesized SI, it is not surprising that contradictory information can be found in peer-reviewed literature covering a specific subject. In such cases, the consensus process increases the likelihood that its outcome would be consistent with the information that will result from relevant future studies.

Pillar: Outside the Purview of Science

One of the most often violated requirements of regulatory science is the inclusion of societal objectives, ideology, beliefs, and numerous other non-scientific issues. On occasion, the regulators claim that they must include societal objectives in their scientific activities to be protective of human health, the ecosystem, and numerous other worthwhile goals. What is being overlooked is that all of these goals, as desirable as they might be, are outside the purview of science and must be addressed after the scientific issues have been resolved. The confirmation of this Pillar is provided by the Ruckelshaus Effect. As stated by William Ruckelshaus "…all scientists must make it clear when they are speaking as scientists *–ex*

cathedra- and when they are recommending policy they believe should flow from scientific information….".

Predictive Models

A large number of SI used in the regulatory process including those dealing with budgets, economics, environment, safety, transportation, human health, and ecology, are based on predictive models. Given the large economic consequences of application of models, it is surprising that in many cases, highly reliable and reproducible models receive nearly the same acceptance as uncertain or speculative models. The BAS/MESC system provides a mechanism to assess the reliability of predictive models.

Applied science: Models that are entirely based on Proven Science or Reproducible Evolving science are, by definition, applied science. For example, models that predict the fall of an item on the surface of the earth are normally based on the law of gravitation. Consequently, they are precisely predictable and the time required for the item to fall can be accurately computed. Similarly, most chemical reactions fall into this category. Many areas of engineering, medical instrumentation, space science, and numerous other parts of industrial production use models that are based on Proven Science.

Primary Predictive Models: Although the foundation of a large number of models particularly those that address contested areas of science is Proven Science or Reproducible Evolving Science, they also use assumptions, judgments, and other tools to develop or apply the model. Therefore, their predictions include inherent uncertainties. Consequently, Primary Predictive Models are entirely Partially Reproducible Evolving Science.

Secondary Models: These models use primary models as their foundation. The predictive ability of these models is significantly lower than those of Primary Models. These models are likely to fall at best into Scientific Judgment. It should be recognized that on occasion a decision maker has no other choice by using these models. However, the decision maker must also be aware of their level of certainty.

Tertiary and Lower Models: These models use secondary models as their foundation. The predictive ability of these models is at best Speculation. The lack of reliability described for secondary models is likely to be more pronounced for tertiary models. Those who rely upon tertiary and lower models must recognize the risk of drawing wrong conclusions form their results. Best on their lack of reliability these models should not be used as the decision tool.

APPENDIX II

INDEPENDENT PEER REVIEW AND INDEPENDENT SCIENTIFIC ASSESSMENT

Peer-review is the foundation of acceptability of scientific claims. Often regulatory agencies need to evaluate the status of scientific information by performing scientific assessment. In the following, requirements applicable to peer review, unless otherwise specified, are also applied to scientific assessment

Assessment of qualification of the reviewers

The peer reviewer is an individual who is capable of performing the project, or that segment of the project that is being reviewed, with little or no study. The process of ensuring compliance with this criterion is demonstrated by:

1. Education in an appropriate field.
2. Sufficient professional experience in an area that is directly related to the topic under review.
3. Peer recognition as demonstrated by serving on relevant panels; election to offices in relevant professional societies; and other activities that indicate recognition by peers.
4. Publication in peer-reviewed scientific journals, patents, and related accomplishments.

Assessment of independency of the reviewers: The reviewer must be independent as demonstrated by the lack of conflict of interest, a set of most complex and contested issues in peer review. Typical conflicts of interest include the following:

1. **Financial Conflict of Interest:** If the reviewer or a member of the reviewer's immediate family would financially benefit from a positive or negative review
2. **Personal Conflict of Interest:** If the reviewer member of the reviewer's immediate family has been materially involved in the project under review.
3. **Institutional Conflict of Interest:** Affiliation with organizations whose activities are being reviewed may constitute conflict of interest. Similarly, unambiguous commitment to an organization with a bias to certain scientific or engineering approaches without consideration of potential alternatives may also constitute conflict of interest.
4. **Intellectual Conflict of Interest:** A preconceived commitment to a certain scientific or engineering approach without consideration of potential alternatives may also constitute a conflict of interest. However, in this case a reviewer with the opposite view may eliminate this form of conflict of interest.

Peer- Review Criteria

The reviewers respond to specific questions called review criteria, often called charge of the panel, review questions, questions for the panel, lines of inquiry, or other terms. Allegations about the shortcomings of peer review are largely the result of inadequate selection or absence of review criteria.

Typically a distinction must be made between generic review criteria and those that are specific to a study that is being reviewed.

Criterion I: Scientific Validity: By far the most important and objective basic criterion is scientific validity. In the majority of cases, compliance with the requirement of scientific validity can be reasonably achieved. Reviewing scientific validity in a submitted manuscript for publication must consider both discipline-specific and Universal Scientific Principles. The scientific validity is particularly critical in scientific information used in regulatory decisions as the societal including economic implications of a failure may be large, sometimes exceedingly large.

Criterion II: Scientific Originality: This criterion is applicable to submissions to scientific journals and funding organizations. The originality implies that the information is new and provides additions to the body of knowledge.

Criterion III: Scientific Creativity: In contrast to criterion on originality, scientific creativity attempts to identify new pathways; entirely new approaches to address a problem; or numerous other approaches that may lead to a scientific breakthrough.

Criterion VIII: Legal Requirements: This criterion includes requirements for studies that include human subjects, those that use radioactive or other toxic materials, and bacteria and viruses.

Criterion IX: Ethical Requirements: This criterion covers issues that are beyond legal or scientific requirements. Many scientific journals require that the authors reveal the source of funding for their study and many professional societies have codes of conduct containing specific ethical requirements.

Criteria for Scientific Assessments

Although there are commonalities between criteria used in peer reviews and those used in scientific assessments, there are also criteria that are specifically applicable to scientific assessments.

Criterion I: The Objective: A scientific assessment is intended to respond to a specific objective based on legal, societal, or other requirement. This criterion is typically broad and describes the mandate. However, depending upon the nature of the scientific assessment, there may by be more than one objective or several sub-objectives.

Criterion II: Reliability of Science: The sponsor of the study and those impacted by the results of the assessment would benefit from knowing the level of reliability of each study or information included in the assessment. It is highly desirable to place each reference or study in one of the following categories described above.

1. Consensus-processed
2. Independently peer reviewed
3. Gray literature
4. Personal opinions

In the past it was common to have information in an assessment covering all four categories including the view of a distinguished individual, implying the validity of the Matthew Effect. Although personal opinion is seldom used in more recent assessments, many continue to contain gray literature

Criterion III: Level of Maturity of Science: As described in Appendix I, the classification of the level of maturity of regulatory science information as follows:

- Proven Scientific Information
- Reproducible Evolving Scientific Information
- Partially Reproducible Scientific Information
- Association-Based Scientific Information
- Hypothesized Scientific information
- Judgment
- Speculation

Consequently, the peer review of a SI used in the regulatory process would require:

1. Identification of assumptions, judgments, and the inclusion of default data in the document.
2. Justification for their selection
3. Performance of sensitivity analysis for the selection of assumptions and judgments and the chosen default to indicate how these selections and choices impacted the outcome

Criterion IV: Inclusion of all Relevant Information: Scientific assessments, particularly those performed by certain regulatory agencies have been criticized for the so-called "cherry picking". Therefore, it is imperative that the process ensures the inclusion of all relevant information.

Criterion V: Inclusion of Non-Scientific Items: Experience shows that many scientific assessments do include areas outside the purview of science claiming that they have societal goals that otherwise would not be met. In these cases, the assessment must not only identify but must also require the justification for the inclusion of areas outside the purview of science.

Transparency

The credibility of peer review is significantly impacted by the level of transparency. For example the process used by the National Academies (National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council) is transparent and includes how the reviewers are selected. Similarly, the process implemented by the Institute for Regulatory Science and overseen by American Society of Mechanical Engineers in cooperation with several professional societies was entirely transparent. As transparency requirements are not always met in peer reviews or scientific assessments the proposed regulatory sunshine would provide a potential remedy.

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