THE NEED FOR REGULATORY SCIENCE TRANSPARENCY AT THE EPA

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Chairman Dr. Harris, Ranking Member Miller, and Members of the Subcommittee; I am A. Alan Moghissi, President of Institute for Regulatory Science (RSI). We were established in 1985 as a not-for-profit organization located in Alexandria, VA and. We are dedicated to the idea that societal decisions notably environmental regulations must be based on what we call "Best Available Science" or BAS. I am a proud charter member of the U.S. Environmental Protection Agency (EPA) and believe that EPA has done an outstanding job in protecting human health and the environment but I am less proud that EPA has missed some opportunities to use BAS in its decisions. I appreciate the opportunity to testify before your Committee and intend to suggest that the time has come for the EPA to substantially expand transparency in the scientific foundation of its regulatory activities.

Science at the EPA and the Establishment of Regulatory Science

Looking back at the history when EPA was formed, although there were laws dealing with air, water, and food, the ability of government to adequately regulate emission of toxic agents was limited. For example, there was no law that provided government for regulating manufacturing of chemicals. During that period the Congress quickly passed a number of laws mandating promulgation of regulations at a rapid pace. Upon the formation of the EPA, the managers and scientists at that Agency were faced with the urgent need to promulgate a large number of regulations based on deadlines mandated by legislative actions or judicial decisions. This problem caused the EPA to rely upon the judgment of scientists, short cutting scientific issues, and use their best to meet the deadlines. During this initial phase of the EPA the phrase regulatory science appeared describing the scientific segments or parts of regulations. Meanwhile regulatory science is defined as follows:

Regulatory science consists of the scientific foundation of policy notably regulatory decisions

Regulatory science, sometimes called regulatory sciences, covers many disciplines (Moghissi et al, 2011). It includes regulatory toxicology, regulatory ecology, regulatory hydrology, and regulatory atmospheric sciences, to mention a few. It is no different than other disciplines such as chemistry discipline that covers, inorganic chemistry, organic chemistry, biochemistry, physical chemistry, chemical engineering, and medicinal chemistry, to mention a few.

As expected virtually all regulatory agencies must deal with regulatory science in promulgating their regulations. For example the Food and Drug Administration (FDA) has not only used that term to describe its scientific objectives but also has devoted significant funds for R&D devoted to regulatory science in areas of its regulatory authority. Similarly, the EPA has an extensive regulatory science program both in its R&D and program offices, although that term is not always used in its pronouncements

With the maturity of the EPA's regulatory process the EPA is provided significant funding for R&D. A discussion of relevancy of EPA's R&D to its mission, the quality of science used in its regulatory process and related issues have been addressed numerous times and most recently, in testimonies before this committee (Anastas 2011, Trimble 2011, Elkins 2011). Therefore, this testimony will address the transparency issue, a subject that appears to have been insufficiently addressed. As stated above, during its initial phases of operation, EPA was facing deadlines and had to go through shortcuts. Meanwhile, the EPA has time to thoroughly evaluate the scientific foundation of its regulations. An example of these regulations is emission limits being considered for greenhouse gases. EPA did not face a deadline and based on its own desire undertook the laborious and highly contested decision to regulate greenhouse gases.

Subsequent to the formulation of the term regulatory science, my colleagues and I tried to develop a systematic process for evaluation of regulatory science information. We had to identify fundamental principles not only for regulatory science but also for any scientific claim. We had also to address how does an organization including a regulatory agency assesses the reliability of a scientific claim regardless of its origin. We struggled for many years to address the level of maturity of scientific information. Finally, we had to address the issue of science vs. areas outside the purview of science. These efforts took over three decades and have reached sufficient maturity that can be described here.

Metrics for Evaluation of Regulatory Science Information

As stated above, the development of the BAS system and Metrics for Evaluation of Regulatory Science Information (MERSI) derived from BAS was the result of extensive efforts to systematically evaluate a number of issues addressing the needs of a large segment of the affected communities, notably regulatory science. The development of MERSI was the consequence of three previous publications. The first formal effort *Best Available Science; Its Evolution, Taxonomy and Applications* (Moghissi et al 2008) contained the fundamental concept of BAS. The next attempt led to the publication of the book: *Best Available Science: Fundamental Metrics for Evaluation of Scientific Claims* (Moghissi et al 2010) that in many respect, was the second edition of the first book. A new version of that book by Moghissi and Swetnam is in preparation. During all of these activities the dominant role of independent peer review in regulatory science was unambiguously described. Consequently, it was logical to prepare a book *Peer Review and Scientific Assessment: A Handbook for Funding Organizations, Regulator Agencies and Editors* (Moghissi et al, in press) with significant applicability to regulatory science.

Fundamental Principles of MERSI

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 (SI) in terms of its level of maturity and its reproducibility.

Class I: Proven SI: 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 are predictable and reliable. As the majority of SI covered in regulatory sciences seldom qualifies as Proven SI, further discussion is not required.

Class II: Evolving SI. The overwhelming majority of scientific advancements and virtually all regulatory science information are included in this class.

Reproducible Evolving SI: 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 Science. Like Class I (Proven SI) information in this class meets the Reproducibility Principle. However unlike Proven SI, the scientific foundation of information in this class is often either unknown or the knowledge is incomplete.

Partially Reproducible SI: Sometimes referred to as Rationalized SI or Scientific Extrapolation this class includes a large segment of regulatory science information including predictive models. Although it builds upon Proven or Reproducible Evolving SI, 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 SI: 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. Experience shows that correlation does not necessarily imply causation and as expected, some correlations have correctly identified their cause but others have proven to be unrelated. A segment of evidence-based medicine belongs to this class.

Hypothesized SI: 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.

SI based on Judgment: In the absence of scientific information, decision makers may call upon scientific experts to make an educated judgment. There is an accepted methodology for this process that involves asking multiple qualified and knowledgeable individuals to answer specific questions and statistically assessing the results. Even so, the results are still tantamount to an educated guess.

Speculation: Speculation does not meet the standards for any of the discussed classes of scientific information addressed above. It is based solely on the opinion and intuition of an individual. 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 SI

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 SI. 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, (ASME/RSI 2002) 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 SI. 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 (Ruckelshaus 1983, Moghissi et al in press) which states that "…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….".

Ethics of Regulatory Science

One of the key issues needing the consideration of legislators and regulators is compliance with ethical principles of regulatory science. Only these principles were only recently formulated, they are readily derivable from ethical principles of virtually all professions notably scientific, 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 in the MERSI system, falls into Proven or Reproducible Evolving SI.

Principle II:

Those who prepare a regulatory science document 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 MERSI principle on transparency. The regulated community, the scientists and their organizations, and the interested members of the public are entitled to know the regulatory science is used in a specific decision.

Principle III:

Regulatory science information must exclude societal objectives thus violation the MERSI 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 if during that period those actions were justified. However the inclusion of societal objectives or ant other subject that is included in "areas outside the purview of science" is not justified.

Principle IV:

Regulatory science information 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 principles I, II, and III of regulatory science ethics.

There is a consensus within the scientific community that peer review is a prerequisite for acceptability of scientific claims. However, the peer review of regulatory science information 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 of the regulatory science participants to promote a specific goal. Similarly,

if societal objectives are included in regulatory science information, they should be not only identified but also justified.

Proposed Roadmap for *Fostering Quality Science* at the EPA

Before addressing the proposed roadmap, it is imperative to recognize that the establishment of the EPA and actions taken by that agency, resulted in a cleaner and healthier environment. It would not be constructive to evaluate the performance of the EPA with the objective to see if EPA could have done a better job. Instead, it is more productive to propose relevant R&D with the objective to improve EPA's performance by enhancing the transparency of the regulatory science used by that agency.

It is proposed to enact the **Regulatory Science Sunshine Act** as a segment of the EPA authorization/Appropriation or as a separate Act. The proposed Act would require that EPA develop processes, procedures, and methods for each regulatory decision that is based on or includes science:

1. 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.
2. Description of the content of all mathematical formulations in words.
3. The information identified above must be written in a language that is understandable to a knowledgeable non specialist or, better yet, to an average person.
4. Clear and unambiguous justification for the inclusion of societal objectives in science rather than addressing societal objectives in the administrative decision process.
5. Obligation of the EPA to comply with ethical requirements of regulatory science

The **Regulatory Science Sunshine Act** would require that EPA makes a concerted effort to develop relevant processes, procedures, and methods to respond to the needs identified above. As many other regulatory agencies face the same problem, such an effort would also benefit numerous other agencies.

Consequences of Regulatory Science Sunshine Act

The opposition to transparency in regulatory science is based on the following:

1. There are those who believe that the "average citizen" is not educated enough or smart enough to appreciate the intricacies of regulatory science.
2. Some of the staff members of regulatory agencies consider that items indentified under Regulatory Science Sunshine Act to be burdensome. After all, whereas scientists in regulatory agencies have a unique competency, others do not have relevant experience and competency.
3. The identification of potential uncertainties would result in the 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
4. Certain 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 foundation of decisions without significant efforts.
5. Members of a variety of advocacy groups also prefer the current situation, as long as the political leadership is supporting them.

6. There are numerous other individuals and groups who are either opposed to transparency or do not care one way or another.

A closer look at the items identified indicates that the following issues are legitimate and must be addressed:

Ability of the Public to Follow Regulatory Science: It is true that a segment of population will have difficulties following the intricacies of regulatory science. However, other segments are capable of comprehending the subject. In addition using as my former boss William Ruckelshaus quoted Thomas Jefferson "If we think [the people are] not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion."

Competency of Regulatory Agency Staff: There is ample evidence indicating that there are scientists outside the regulatory agency who are as competent or more competent in relevant areas of regulatory science than the staff members of the relevant agency. This subject is well recognized by reliance upon peer review.

Decisions Based on Uncertain Scientific Information: By far the most critical issue in the proposed legislation in the legitimate issue of convincing the public that a decision is necessary in the interest of the society. It should be recognized that societal decisions based on incomplete and uncertain scientific information is more common than may appear.

The example of meteorology can be used to demonstrate the point, a discipline that provides short term weather forecasting. Most cities rely upon forecasts on snow and its severity and use them to mobilize the necessary personnel and ensure availability of relevant equipment. Similarly, governmental agencies make decisions on both positive and negative consequences of the predicted rainfall.

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 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.

The EPA and other regulatory agencies have the legal and ethical obligation to inform the public to the best of their ability the status of the science used in their regulatory decisions. The information must include assumptions, judgments, the inclusion of default data, and any other information that impacted the scientific aspects of their decision.

Conclusions

The **Regulatory Science Sunshine Act** would require a reorientation of the EPA's R&D with the objective to develop processes, procedures, and methods for transparency in regulatory decisions. EPA should be required to identify assumptions, judgments, default data, or other similar systems used in the regulatory process, identify potential alternatives, and how the conclusion would be different if alternative assumptions, judgments, and similar parameters were used. In addition,

EPA should attempt to describe the content of all mathematical formulations in words. Furthermore, the Act should mandate that EPA makes a concerted effort to describe these activities in a language that is understandable to a knowledgeable non specialist or, better yet, to an average person.

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