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Madam Chairman and Members of the Committee, I appreciate the opportunity to testify on the use of science in environmental regulatory policymaking. Over the last 29 years I have participated in or witnessed the use of science in policymaking as a Congressional Science and Engineering Fellow of the American Association for the Advancement of Science, a Congressional staff person for 12 years, as a senior manager in the National Academies of Science's and Engineering's National Research Council, in the private sector, and in the Executive Branch. In the Executive Branch, I served in the Office of the Secretary of Energy, as Associate Director of the Office of Management and Budget (OMB) for Natural Resources, Energy, and Science, and as the Assistant Administrator for Research and Science Advisor for the U.S. Environmental Protection Agency (EPA).

Any student of the policymaking process is quickly struck by the wide variety of factors that influence the decision-making process in policy formulation. Science is just one of these factors. Other factors include how different policy options will affect our economy, our different cultures, and the quality of our life and environment. The process cannot be separated from the differing political philosophies of the players making the decisions. Certainly, as the members of this Committee know, these decisions are made with attention to the opinions of the public.

Currently, there is much discussion about whether the policy should be dictated by the science or the evaluation of the science should be dictated by the policy option selected because of other factors. Given the reality that science is one of a number of the factors evaluated, the question should be, "What weight should we give science in formulating policy?" A further complication arises when there are significantly different views within the scientific community as to how "good" the science is or what the science "says."

The weight science should have in formulating policy depends on the quality of that science, what a fair characterization of the science indicates, the uncertainties surrounding that science, and the magnitude of the consequences of the different policy options.

<u>Quality of Science</u>

The EPA is expected to do high quality science and at the same time to be at the leading edge of the development of new techniques and analytical approaches. So, while

performing a health assessment on a compound for inclusion in the Integrated Risk Information System (IRIS) it may also be introducing a new way of assessing the health effects of the compound. One of the keys to the best use of science in the regulatory process is to have people within the regulatory agency actively engaged in that science. This model is still in practice at the EPA. It has disappeared at the Nuclear Regulatory Commission and Food and Drug Administration. This Subcommittee is probably aware that the funding for scientific research at the EPA has been, at best, constant for over 20 years and in some fields it has been declining. The EPA will not operate at the leading edge of science in the future with a resource picture like that. This is especially important because we continue to learn new things that change the regulatory landscape. We thought we had solved the lead problem. We thought our regulations for ozone were appropriate. In the early 1990's we were comfortable with the regulation of particulate matter in our air. But new science meant that new regulatory decisions were in order.

Significant steps have been taken recently in an effort to improve the quality of the science used within the Environmental Protection Agency (EPA) for regulatory policy-making and for implementing policy. The Information Quality Guidelines and the Peer Review Standards for Regulatory Science are two examples of efforts aimed at improving the process of quality assurance in the use of science by the federal government. The peer review process at EPA today has evolved, with continuous improvement since the early 1990's. The agency is now the recognized leader among federal agencies in the use of peer review. Dr. Matanowski of the Johns Hopkins University serving on the EPA's Science Advisory Board said before the House Science Committee, "I think EPA has taken massive steps to improve their peer review, and the Science Advisory Board is not the only place…from what we have looked at in the EPA, they have done an extremely good job getting almost everything that they look at now peer reviewed." (House Science Committee – April 2002)

Much has been done to make the process more transparent. For example, EPA now has a database on the internet that lists all the scientific work underway, the plans for its peer review and the status of those plans (see http://cfpub.epa.gov/si/). The EPA has also made very significant progress in establishing a process for validating the computational models that are so integral to modern regulatory science and making them more transparent (see http://cfpub.epa.gov/crem/knowledge_base/knowbase.cfm). It is essential that computational models be credible because they, along with remote sensing, are revolutionizing our ability to assess environmental conditions and threats to the environment.

There are gaps in some agencies' quality processes. Some are not even within the control of the agency. For example, while EPA has a Quality Assurance/Quality Control process for the generation of data within its laboratories, there is no comparable system within academic laboratories that generate the majority of information used by regulatory agencies like the EPA. This was identified as a significant problem for implementing the Information Quality Guidelines. It is not usually possible to evaluate the methods used and the quality of the data generated by non-EPA scientists when the results are gotten from peer reviewed literature. This is because there are significant constraints on the

authors due to space limitations in these journals. Let me underscore the point I have just made. The EPA does not, nor ever has had, the resource to fund all the research it would need to have the kinds of information that is ideal when it performs a health or environmental assessment. It must rely on the scientific research published in the open literature.

Characterization of the Science

Make no mistake about it – the science we are talking about is difficult to perform and to interpret. The process of synthesizing the results of all the research and fairly characterizing the "bottom line" is the most contentious step in the process. More needs to be done by federal agencies to explain and standardize this process of characterizing the science, especially when there are conflicting lines of evidence. In the absence of this, we have come to rely on the peer review process to judge the quality of this characterization step.

Uncertainty of the Science

It is the rare scientist who will express absolute certainty about their science. Policymakers working on environmental issues are painfully aware of this. In fact, if they do profess certainty, take it as a warning sign that there may be a problem with their science. The discussion is always about the magnitude of the uncertainty. Uncertainty is generated throughout the scientific process. In taking measurement, there is uncertainty introduced. That is why repeating measurements, taking multiple samples, and replicating experiments has become a fundamental part of the process. Uncertainty is introduced in the analysis of data and its use in computer simulations. In the past decade, an increasing emphasis has been placed on techniques to quantify the uncertainties in the science. Some agencies of the federal government have been slow to adopt these techniques. Doing so will improve the ability of policymakers to evaluate the weight they should place on the science in their decision-making. However, it would be a mistake to suggest that science has no value when there is uncertainty. Sometimes uncertainty is a distinguishing and inherent character of the system we are studying. For example, today we have the ability to predict weather quite accurately over short periods of time. When we begin to make ten day forecasts, our accuracy falls. It is not because we do not understand how weather works. It is because the atmospheric interactions are so complex that they are not easily predicted on this somewhat longer time scale.

Whose Science is the Right Science?

In the 1970's, the terms of environmental policy debates were different. Often the critic of a particular policy option would argue that the cost of compliance "per life saved" was excessive. Rarely was this approach fruitful. It became clear that many were willing to ask that the high cost of compliance be paid - as they viewed the life saved might be their own. The grounds of the debate have shifted. It is now often about the quality of the underlying science. I would hazard to guess that every member of the Senate's Environment and Public Works Committee has, on one or more occasions, taken

the EPA to task for the quality of its science on behalf of their constituents. And each and every member has probably found themselves accusing the agency of "ignoring" the science when a policy decision is at variance with the wishes of their constituents. But that is a debate in which every scientist inside the agency should be willing to engage. It is unlikely that there will ever be unanimous consensus on a scientific issue underlying any given policy. The greater the potential consequences of selecting a given policy option – in economic terms or terms of quality of life or the environment – the more lively the debate over the science will be. The scientific bottom line is rarely easy to perceive. It is rarely "black or white." In the end we rely heavily on scientific judgment for the scientific portion of the information used by policy-makers. Our best insurance that the science, the scientific judgment, and policy-making are as good as they can be is that the process is transparent, participatory, peer reviewed and followed with informed oversight.