Bob,

Never ask an "old war-horse" for an opinion, you may get one. Here is a weekends worth of reflection on a lifetime of experience. Use it as you see fit.

The oversight committee appointed by the Administrator to recommend those actions which should be taken to improve the scientific foundation of EPA policies, programs and regulations has been given an immense task. " Improve the science". A phrase that rings of motherhood and apple pie. The more you ponder the question, the foggier it becomes. " Improve the science" to do what? Make money? Control the rate of change so that no one looses money? Avoid policy conflicts? Control the rate of change so that no one looks bad? The phrase is undefined and indecipherable without being placed in the context of agency goal and functions needed to achieve that goal. What does the Agency wish to achieve through its science program?

For me, the Agency draws it legitimacy from a public health mandate to establish and enforce national standards which control the cumulative daily exposure of a chemical, physical or biological agent to a level that is low enough to insure that citizens, young and old, do not experience biochemical changes which impair normal physiological function causing a precondition to disability, disease or death. Within this framework, the objectives of Agency "science" would include:

* identifying all of the impacts which an agent is reported to have in biological systems.

* ascertaining the level of certainty associated with each reported end point.

* calculating the best estimate of dose required to evoke the end point.

* identify the physical, chemical or biological processes which may modify initial environmental levels.

* participating in agency mechanism to ensure that this knowledge is incorporated into policies and regulations in a manner which assures that the public health impacts of an allowable dose is clearly presented for public scrutiny.

* promoting the development of critical information needed to perform these functions in a timely manner.

Now, what is necessary to improve our ability to achieve these science objectives? Let's try to get down to specifics.

Objective 1

* identify all of the impacts which an agent is reported to have in biological systems.

Information of this nature is housed in three sources, published peer reviewed literature, non peer reviewed reports, and current research findings that have not yet been published. The information base is also constantly changing.

- a huge net must be cast through each of these areas to obtain abstracts of papers.
- the information must be sorted by topic area.
- critical papers in each area must be identified.
- the original papers must be obtained.

All of these functions can be provided by support personnel and apprentice scientific personnel. The function must be repeated at reasonable intervals to assure that decisions are still in accordance with "new" knowledge.

Objective 2 * ascertaining the level of certainty associated with each reported end point.

Judgements about the content of critical papers must be made by scientists with specialized training in the area they are reviewing. These specialists mus also understand the goal they are helping to achieve and the need to tailor assumptions to be in concert with the philosophy underlying the goal. Several questions appear central to the review of critical papers. These questions should be used to guide the discussions and decisions. For example:

How certain can we be that a reported finding is real and reproducible rather than an artifact of experimental design?

Do the data support the authors conclusion?

How would the reported effect be exhibited in an exposed individual?

Object 3 * calculating the best estimate of dose required to evoke the end point.

Published papers and conversations with authors may allow estimates to be made for some end points. However in most cases the transformation from animal data to man requires a series of mathematical manipulations based upon a set of assumptions. Specialists presenting the dose estimates must also present the series of assumptions upon which the findings are based.

A profile of each chemical thus derived should then be reviewed by a body of senior personnel capable of understanding the content of findings being presented by the specialists and acting as a sounding board to judge the logic supporting the conclusions reached including the assumptions.

Individuals participating in the review process must be insulated from rewards or punishments resulting from the content of their findings.

Objective 4 * identify the physical, chemical or biological processes which may modify initial environmental levels.

Biological, chemical and physical processes inherent in the receptor organism and the environment have a profound influence on the dose resulting from initial environmental releases. Dilution, concentration, drift, deposition, resuspension, binding and activation are processes common to all pathways of exposure. These agent specific processes must be recognized so they may be incorporated into media related guidance and recommendations. Once again key questions should be provided to guide specialists and a review process is needed to validate the assumptions, logic and findings.

Objective 5 * participating in agency mechanism to ensure that this knowledge is incorporated into policies and regulations in a manner which assures that the public health impacts of an allowable dose is clearly presented for public scrutiny.

This is a function for very special people who are willing to face the conflicts of working to forge public policy. Senior people who are dedicated to the mission of the agency should probably be involved.

Objective 6 * promoting the development of critical information needed to perform these functions in a timely manner.

This classical research need must be judged by its ability to meet the needs of the process described above.

Each of the objectives can only be met if agency leadership establishes an environment nurtures individuals who work to fulfill the critical functions associated with each objective. Professionals should recruit professionals. Peers should rate the performance of peers. Collegiality and group discussion must replace isolation. Individuals should be assigned work on the bases of their training and experience. Reviewers should not accept work from anyone other than the responsible professionals. Professionals should be accountable for their work. Each piece of work should bear the name of individuals responsible for the findings. Administrators should administrate and should not be empowered to affect scientific content. Administrative personnel should have an equal or lesser status than individuals in the science tract.

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