PUBLIC HEALTH DECISION-MAKING AND RESOURCE ALLOCATION: DIOXIN AND OTHER PBTS AS A CASE STUDY

SETTING PUBLIC HEALTH PRIORITIES

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Introduction

Focusing public health resources where they will have the greatest impact requires constructive thinking about risk management goals and choices. An examination of how regulatory agencies use science can be explored by using dioxin research as a case study. Substantial effort has gone into the most recent EPA assessment updating what is known about dioxin. Yet, the assessment does not appear to have been conducted with a clear context for whether dioxin remains a priority within the range of public health risks facing Americans and, accordingly, what problem EPA is seeking to solve. Thus, we do not know how dioxin fits into the current patterns and trends of the major threats to morbidity and mortality in the US, and what this means for risk management. Nor does EPA reconcile the conflicting messages that the cancer risk from dioxin could be as high as one in one thousand, that our primary source of dioxin exposure is through food, and that children are exposed to dioxin through breast milk while at the same time, that our food supply is safe and that children should continue to breast feed.

Public health agencies like the EPA depend on high-quality science. Without high-quality science, their public health efforts aimed at the prevention of disease and the promotion of health can neither identify the causes of diseases, nor achieve their prevention. Indeed, without high-quality science available to measure productivity of public health programs, the effectiveness of public health agencies themselves cannot be measured.

Public health agencies are subject to criticism regarding the sufficiency of their science and processes used to achieve their public health objectives. For example, regulatory agencies' use of science to identify hazards and develop regulations for those hazards has been criticized for issues such as (i) the blurring of the distinction between "science" and "policy" as the basis for decision-making; (ii) the science not supporting the regulatory alternative selected; and, (iii) the science-based decision processes for selecting agency priorities or developing regulatory alternatives without sufficient transparency.

Methods and Materials

The project entailed the examination of various expert views, i.e., papers, reports and books examining the use of science by regulatory agencies.

Results and Discussion

According to expert commentators, criticisms about regulatory agencies' use of science arise from the very nature of the evolving scientific discovery, and the degree of uncertainty that is associated with science-based decisionmaking. As a science-based regulatory agency, EPA makes decisions on health concerns for which scientific information may be incomplete or missing. Indeed, for many of the adverse health outcomes that EPA seeks to avoid, human epidemiological data is limited or does not exist, and the agency relies on surrogate data or otherwise analogous information. Thus, questions arise regarding whether the use of particular surrogate data or analogous information is appropriate as a matter of science or agency policy.

Perceived insufficient transparency revealing how EPA conducts its work has raised concerns by groups ranging across the political spectrum. Indeed, concerns regarding insufficient transparency contribute to the "…widespread perception that many EPA decisions do not reflect the best scientific analysis and that the agency lacks adequate safeguards to prevent science from being adjusted to fit policy[1]."

Associated with inadequate transparency are criticisms regarding the methods by which the agencies utilize science in the regulatory decision-making process, and the extent to which decisions are made based specifically on the science or agency strategy. These scientific and organizational concerns contribute to the three common problems of science-based regulatory agencies described by Justice Steven Breyer[2]. *Tunnel vision*: the "single-minded pursuit of a single goal [carried] too far, to the point where it brings about more harm than good." *Random agenda selection*: the "problem with the creation of regulatory agendas and with the establishment of rational priorities among the items that are included in those agendas." *Inconsistency*: discrepancies in approaches to regulation within and among agencies and programs. Possibly, a most harmful aspect is that the regulation of small risks can produce inconsistent results, thus causing more harm to human health and the environment than it prevents. Justice Breyer ascribes these problems to three principal causes: public perception, Congressional action and reaction, and uncertainties in the technical regulatory process.

Various solutions have been proffered to strengthen science-based decision-making for public health in public health agencies such as EPA. These range broadly from elevating EPA to cabinet level status, transferring science functions from the EPA to a separate environmental problem identification and research organization similar to the split between the Occupational, Safety and Health Administration and the National Institutes of Occupational Safety and Health, or simply adding a new EPA Deputy Administrator for Science.

The government should have a coherent overall approach to public health and all public health agencies including EPA must strive to use the highest quality science in their efforts to protect public health. Accordingly, the administration, public health agencies including EPA, the public and the country will benefit from improvements designed to ensure that:

1. Public health efforts across the government are appropriately led and coordinated;
2. The public health science supports the selection of agency priorities and development of regulatory alternatives;

3. Public health agencies, including EPA, distinguish between science and policy in their decision-making and communicate in a transparent manner the bases for their decision-making; and
4. Decisions intended to protect public health take full advantage of the expertise of agencies, associations, and/or individuals with broad public health expertise.

The administration needs to develop a set of criteria upon which it bases its decisions regarding the protection of public health (for example, will the focus be on morbidity or mortality?). And each agency should define the bases it uses to determine changes in prioritization of important public health concerns from year to year. Finally, there should be periodic evaluation of completed agency actions with an associated assessment of the action's impact on public health.

To achieve these objectives, one proposal would be for an overarching, periodic, public health priority setting review by a White House organization such as the Office of Management and Budget (OMB), the Council on Environmental Quality (CEQ), or the Office of Science and Technology Policy (OSTP). For this, the administration would need to establish a set of criteria upon which to base its priorities for decisions regarding the protection of public health. These criteria for prioritization of different public health activities could be achieved by a White House led interagency group, or by a national commission that could develop a broader consensus.

References

[1] Powell, M.R. 1999. Science at EPA. Information in the Regulatory Process. Resources for the Future. Washington, DC.

[2] Breyer, S. 1993. Breaking the Vicious Cycle: Toward Effective Risk Regulation. Harvard University Press. Cambridge, Massachusetts.