Honestly, What Is The Best Science?

By **William Walsh, Clark Hill PLC**April 25, 2017, 4:38 PM EDT

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When it comes to regulating chemicals, most stakeholders support the use of the "best science." However, there appears to be little agreement concerning what "best science" means, how to weigh studies to reach a conclusion as to what the science is saying, and the appropriate balance between science and policy in regulatory decision-making.

U.S. Environmental Protection Agency Administrator Scott Pruitt and the new EPA political appointees must wrestle with the difficult scientific, policy and legal questions involved in regulating existing chemicals. No doubt, there will be a vigorous debate over which interpretation of "best science" the new administration should (or must) apply in developing regulatory requirements. It is therefore timely to review briefly these science policy issues and speculate over whether there is any hope that there are opportunities to reach consensus on this issue. The purpose of this article is to explicate (or at least attempt to explicate) the varying positions concerning the use of science in the regulatory process and touch on the potential for reaching consensus.

First, some stakeholders object to codifying the use of the "best science" and similar requirements because it allegedly shifts the decision-making from scientists to legislators and the courts.[1] Simply put, they argue, science should be decided by scientists without "interference" from Congress, regulators or the courts.

Although this concept has some appeal, many industry stakeholders note that "best science" and similar terms are already incorporated into statutes. For example, Congress directed federal regulatory agencies generally to use the "best available science" or similar language in the 2002 Information Quality Act.[2] Other media-specific statutes also contain best science directives (e.g., the 1994 the Safe Drinking Water Act and the amendments to the Toxic Substances Control Act (TSCA amendments)) and Congress is considering adding similar language in future statutes.[3]

More generally, stakeholders and even scientific review bodies cite the fact that the information utilized in making environmental decisions relies "heavily on default options or generic approaches," which "lead to risk estimates that, although plausible, are believed to be more likely to overestimate than to underestimate the risk to human health and the environment."[4] As a unanimous ruling of the D.C. Circuit candidly noted, risk determinations are not based on scientific proof of harm, because the risk from exposure to chemicals at extremely low environmental levels is more a function of "the rule of arithmetic rather than because of any knowledge" and there is "no particular reason to think that the actual line of the incidence of harm is represented" by the assumption selected by the EPA.[5] Thus, the chemical regulation process is inherently part science and part science policy and historically has always been in the hands of the regulators with oversight by the courts, based on the criteria set forth in the statutes, not just the judgment of scientists.

Further, it is argued that inclusion of the "best science," weight of the evidence, and similar

science policy requirements in statutes provides a transparent basis for the regulated community and other stakeholders, agency policymakers and ultimately the courts to understand the basis for the decision. As a result, it is critical to transparent chemical regulation to distinguish between science and science policy and to get the science right.

Second, some environmentalists note that the concept of erring on the side of caution when faced with scientific uncertainty or limited data to protect the public is embedded in all environmental statutes. Some argue that even the EPA's existing balance of policy and science to resolve uncertainties in favor of protecting human health is not sufficient and that "precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically."[6] They maintain that to protect children and other vulnerable or susceptible populations adequately, the EPA should simply adopt a "better to be safe than sorry" policy (i.e., virtually any risk-reduction action is warranted unless the cost renders the action infeasible).

Moreover, the EPA's staff has stated at public meetings on the TSCA amendments implementation that the EPA's TSCA risk evaluation rule need not modify the EPA's standard risk assessment or evaluation criteria because the EPA already uses the "best science."

Some industry groups and scholars cite U.S. Supreme Court Justice John Roberts: "In a democracy, the power to make the law rests with those chosen by the people. Our role is more confined — 'to say what the law is.' … But, in every case we must respect the role of the Legislature, and take care not to undo what it has done."[7] Therefore, in assessing the role of science in a rulemaking, one must start with the explicit language that Congress included in a number of statutes and the congressional intent underlying that language (if it is clear).

Industry notes that, except for the now long-repealed Delaney amendment to the food and drug laws, no statute has simply barred the presence of a toxic chemical in food or the environment regardless of concentration. In this situation, industry groups argue that the inclusion of "best science" language repeatedly in statutes does not appear to be an afterthought or mere surplusage, but was purposefully added to each of these statutes at the insistence of Congress which was quite mindful of claims that the EPA's existing risk assessment process had shortcomings.

Some industry representatives cite serious scientific deficiencies or inconsistencies in the EPA's risk assessments and evaluations found in some recent reviews of the EPA's decisions to justify adding "best science" and associated language to environmental statutes.[8] For example, one National Academy of Science (NAS) report tasked with advising the EPA concerning whether EPA's formaldehyde risk assessment was scientifically valid concluded more broadly that the EPA failed in many risk assessments to apply properly the weight of the evidence in regulatory contexts and that "multiple groups" had identified "persistent problems" with the EPA risk assessment approach.[9] In fact, NAS concluded that sometimes the EPA's "conclusions appear to be based on a subjective view of the overall data" and identified an "absence of a causal framework." Other critics claim that some studies cannot be replicated; some hazard conclusions are contradicted by other EPA decisions, state evaluations, NAS reports, the EPA's Science Advisory Board reports, or other independent expert panel's reviews. It is beyond the scope of this article to assess

the merits of these and other claims or the EPA's explanations, but these evaluations raise serious questions and have been raised by serious people.

Third, environmentalists argue that industry is too influential in the regulatory process and seems to advocate consistently for less regulation.[10] Scientific decision-making should rest with scientists, not legislators or the courts, they say. As a result of the inequity in resources between industry and others, and because the central policy of the existing statutes is to protect human health, some even advocate that industry's participation should be restricted. In the most extreme example, if Sen. Frank Lautenberg's original bill (S. 847 — 112th Congress: "The Safe Chemicals Act of 2011")[11] had been enacted, the EPA's risk-reduction decisions would have been exempted from judicial review. As a result, industry's ability to seek independent review of the EPA's risk-evaluation decision would have been entirely eliminated.

Industry stakeholders, on the other hand, point to the situations where research that identifies a substantial risk was performed by industry and was followed by risk-reduction action, to challenge the assumption that industry science is inherently biased. They argue that the very nature of science requires scientists to propose hypotheses and then seek to transparently probe their validity. A process that fails to challenge EPA proposals is inherently less reliable. Furthermore, even with the best of intentions, by utilizing enough science policy assumptions and safety and uncertainty factors, any regulatory limit can be driven down to a level far below ranges that cause actual harm. If regulatory resources are used to address one chemical, it means that those resources cannot be allocated to reduce the risk from another source. Moreover, even those who favor strong regulation should be concerned that making claims of significant risk, when there is little evidence, can result in the loss of public trust, which undermines all regulation.

Industry, of course, points out that barring judicial review (as was proposed in the Safe Chemicals Act of 2011) raises fundamental due process concerns. Even those accused of the most heinous crimes are entitled to a defense.[12] Not surprisingly, Congress has never exempted EPA risk assessments from judicial review (e.g., the final TSCA amendment contains no such exemption).

This article (albeit not exhaustive) illustrates that there are substantial differences between the various advocacy positions. In most respects, the differences revolve around the magnitude of the safety and/or uncertainty factors used in the typical risk evaluation process. It should come as no surprise that the likely Trump administration science policies may differ from those of the previous administration. Such has always been true for the long history of environmental regulation.

The question for the new administration to answer in implementing statutes going forward (and the courts in interpreting the regulations that flow from these statutes) is what did those "who were chosen by the people" mean by adding these words to these several statutes. The administration and the majorities in the House or the 60-vote supermajority that may be needed in the Senate in more situations clearly have more leverage than historically has been the case, where divided government is more often the norm.

Prior administrations have relied upon their election mandates to justify changes in policy. Some public policy commenters argue that science policies worked out through a

transparent and fair debate (which is not necessarily an easy process) will last longer and be less likely to lead to seesawing of policy. It should not be assumed that consensus (or compromise) is impossible. Congress managed to bridge partisan differences in enacting the TSCA amendments as recently as June 2016. Similarly, in the 1980s, the EPA was able to develop a stringent, but workable, approach to setting cleanup levels at hazardous waste sites, even though the EPA had been urged to use zero as the goal. Thus, we do not yet know for certain, which past will be our prologue.

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[1] Written Statement of Andrew A. Rosenberg of the Union of Concerned Sciences, Before the U.S. Senate Committee on Homeland Security and Governmental Affairs (March 9, 2017) ("Rosenberg 2017 Testimony").

[2] Information Quality Act (Sec. 515 of the Treasury and General Government Appropriations Act for FY 2001, Pub. L. No. 106-554), the Office of Management and Budget (OMB) issued government-wide Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (2002), 67 Fed. Reg. 8452 (Feb. 22, 2002) [hereinafter Information Quality Guidelines], available at: https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-24.pdf.

[3] The Honest and Open New EPA Science Treatment Act of 2017" ("HONEST Act") has passed the House and is being considered by the Senate Committee on Environment and Public Works (available at https://www.congress.gov/bill/115th-congress/house-bill/1430/text?r=61.. If enacted, it will require, among other things, that "all scientific and technical information relied on" in promulgating a regulation or in EPA guidance must be based on the "best available science" and studies be "publicly available online in a manner that is sufficient for independent analysis and substantial reproduction of research results, except that any personally identifiable information, trade secrets, or commercial or financial information obtained from a person and privileged or confidential, shall be redacted prior to public availability." A similar bill passed the House in the previous sessions as the "Secret Science Reform Act."

[4] National Academy of Science ("NAS"), Science and Judgment in Risk Assessment (1994).

[5] Natural Resources Defense Council v. EPA, 824 F.2d 1146, at 1164–65 (D.C. Cir. 1987) (unanimous en banc decision).

[6] The Wingspread Conference on the Precautionary Principle (January 26, 1998), available at http://sehn.org/wingspread-conference-on-the-precautionary-principle/. In the decades since its first enunciation, this general statement has come to be interpreted as requiring less and less of a scientific burden of prove.

[7] King v Burwell, 135 S.Ct. 2480, 2488 (2015).

[8] Written Statement of Nancy B. Beck, American Chemistry Council, Before the U.S. Senate Committee on Homeland Security and Governmental Affairs (March 9, 2017). This articles does not summarize each of these claims or EPA's and environmental groups rebuttals.

[9] NAS, Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011).

[10] Rosenberg 2017 Testimony, supra note 1.

[11] www.GovTrack.us. 2011. April 20, 2017 https://www.govtrack.us/congress/bills/112/s847.

[12] To quote A Man for All Seasons, "I'd give the Devil benefit of law, for my own safety's sake!" Available at http://www.goodreads.com/quotes/7515521-william-roper-so-now-you-give-the-devil-the-benefit.