

Comments from Drs. Joseph Gardella and Richard Smith, Co-Chairs, SAB Science and Transparency Rule Workgroup

Key Issues to be Considered in Discussion of the Science Advisory Board Draft Report on EPA's Proposed Science and Transparency Rule

The SAB Draft Report comprises a cover letter with an overview of the issues, the membership of the SAB and the Draft Report itself beginning with a Table of Contents. Within the Draft Report, there are three sections, numbered 1-3 and a reference list. Section 1 is the three and one half page Executive Summary, followed by Section 2, a short Introduction, and section 3 entitled *SAB Advice and Comment on the Proposed Rule*. Here are a few detailed points developed to help organize thoughts and comments about the components of the draft report.

1. What is raw data. The proposed rule does not make clear what the EPA considers to be raw data, whether it suffices to provide computer-processed data or whether it is necessary to go back to original reports (e.g. handwritten lab reports of toxicology studies). There is a separate issue of how to treat historical data when the original reports or data from testing/analysis no longer exist.
2. Privacy and legal issues. We recall the comment of one speaker in Friday's session that a paragraph on page 16 ("The SAB notes that there are legitimate legal, ethical, professional and financial reasons...") should have been in the letter to the administrator, and we agree. The rule will not achieve its stated purpose if its effect is to exclude a large fraction of available studies and this may violate the Clean Air Act (which called for "best available science", but said nothing to equate that with transparency). This issue is critical to our evaluation of the whole rule.
3. The weight of evidence question. As we understand it, the issue is whether the proposed rule applies to all studies cited in a weight of evidence analysis, or only to the studies that are directly cited in justifying a particular rule. Evidently, the latter interpretation would be less burdensome.
4. Case by case exceptions. The rule states that the administrator may, at his discretion, waive the transparency rule in certain cases, but gives no indication of what are the scientific criteria that may justify such exemption. This is closely related to the privacy concern: if we had indication that the administrator intended to exempt a study from the rule where there were genuine privacy issues, that would alleviate a lot of the concern that has been expressed, but we have had no indication that this is in fact the intention.
5. Dose-response curves. The proposal makes some rather strong requirements on the form of dose-response function used in toxicological studies. We feel that trying to impose the form of dose-response function runs against established scientific and statistical practice that would require each case to be treated on its own merits.

Science Advisory Board (SAB) Comments to Assist Meeting Deliberations (1/21/2020). These comments do not represent consensus SAB advice or EPA policy. DO NOT CITE OR QUOTE

6. Costs. There are two different kinds of financial costs associated with this proposal. The first is the cost of actually complying with it: who would pay for the extra staff time required and the physical costs (e.g. renting server space) that would be required to store data in a form accessible to the public, with appropriate documentation? The second kind of cost is the cost involved in actually performing a reanalysis: who is going to do it, and who will pay for it? Our sense is that EPA has not thought about this point at all.