#### EPA ANNUAL SCIENTIFIC INTEGRITY STAKEHOLDER MEETING

# May 27, 2015 Hosted by the American Chemistry Council

#### Welcome and Introductions:

 Dr. Rick Becker of the American Chemistry Council (ACC) opened the meeting and introduced Dr. Francesca Grifo (OSA), the EPA Scientific Integrity Official (ScIO). There were 50 attendees.

## Dr. Grifo's Presentation:

Dr. Grifo presented PowerPoint slides conveying the historical context of EPA's Scientific
Integrity Policy (Policy), how the Agency defines Scientific Integrity, current initiatives, the
status of allegations and other aspects of the Policy's development and implementation. Dr.
Grifo emphasized the importance of public trust.

### **Question and Answer Period**

- Dr. Larry Reiter, a public member of the ACC Strategic Science Team, asked who determines what constitutes the "timely" release of scientific information. Dr. Grifo responded that there is a strategic window within which to release information. For example, if a document is final on January 1, that does not mean it must be released January 2. Factors such as external developments and circumstances affect when a document might appropriately be released, although one year would very likely not be justifiable as a strategic window. Each instance will be different.
- Dr. Reiter elaborated by presenting "two sides of the coin" regarding timeliness and asked how Dr. Grifo's office might respond in either case. In one instance, data are generated and are being moved into peer reviewed publication but have not yet reached completion of the process; however, the data are of great interest to a regulatory program that wants to use them before the data have completed the peer review process. In the other instance, a report might not be ready for peer review, but it might be somewhat inconvenient for the report to be released by EPA given some other policy or ongoing activity within the Agency. What is the role of Dr. Grifo's office in dealing with such situations? Dr. Grifo responded that her office looks into situations that are brought to her attention. If someone charged that a publication was being held up by EPA, her office would look into it. In a recent case, through discussions with key personnel, a report was released after approximately 2 months. Dr. Grifo noted that she has not observed "nefarious delay," only delay as part of a strategic release within a broader context of interests and goals. Dr. Grifo's office does not have the staff to serve as "timeliness police," but she can respond to allegations. Discussions have proven extremely effective.

- Jamie Conrad of Conrad Law & Policy Counsel noted that the logic model Dr. Grifo presented in her slides identified public trust in the Policy as an outcome. In the 2014 annual report, 11 of the 40 allegations referenced were formal allegations filed by external entities. He asked when, and to what extent, Dr. Grifo could provide information about the kinds of issues and circumstances raised in the allegations; trust in the process requires some transparency about the outcome of the allegations made. Dr. Grifo agreed, and noted that in the 2014 report her office had adjudicated only one allegation, which the report summarized. The summary, however, excluded details. The allegation was not substantiated, and Dr. Grifo's office does not want to adversely affect a person's career by reporting unsubstantiated allegations. She acknowledged that adjudications of allegations are not being processed as quickly as she would prefer. Her office consists of herself and one full-time employee, and they are the only two staff working on allegations as well as other activities, for which there is some additional support from a fellow and a student contractor. Allegations, however, are government business and can only be adjudicated by government employees. It is more important to build trust that enables allegations to come forward than to publish potentially unsubstantiated charges that could harm a career. There is a tension between these goals.
- Mr. Conrad added that, with EPA's action development groups, much of the Agency's scientific work is derived from large numbers of people, so many times allegations are not directed at individuals but at processes. In those cases, providing explicit information about the allegations would not harm specific individuals. Dr. Grifo responded that her best recollection of the 62 allegations is that none pertain to process. She agreed that if they addressed large formal processes Mr. Conrad's point would be correct, and if the allegation points to a large group of people rather than an individual, her office would be more comfortable publishing a summary.
- Martin Stephens of Johns Hopkins University asked Dr. Grifo to elaborate on the idea of "insulation from bias" in the research context. He asked if the idea referred to the standard risk of bias considerations, such as random allocation, or a higher level effort to insulate EPA's science from bias. Dr. Grifo responded that at a higher level there are many conflict of interest constraints in place at many different levels. As with "timely" allegations, the ScIO responds to allegations, which currently would pertain to the more ordinary bias considerations that Mr. Stephens mentioned. Her office, however, is always open to hearing about bias at either level.
- A participant ("Ray") inquired about the Policy for dissent from Agency decisions. Noting that no organization likes criticism from staff once a policy decision is made, he asked how Dr. Grifo's office handles dissent, either as a strictly internal or public matter.

Dr. Grifo responded that initially dissent is internally managed, with the goal of resolving concerns at the office level through discussions. If that fails, then a dissenting view will be written so that it can either move with the majority view or be part of a charge to peer review; if peer review does not resolve the matter, it becomes a document attached to the decision potentially all the way up to the decision maker, including the Administrator if that is the person making the decision.

• Dr. Becker noted that a slide presented by Dr. Grifo highlighted EPA's *Risk Characterization Policy*, which external parties consider to be a good document but not implemented as much as it should be. He asked if Dr. Grifo highlighted the document to emphasize that it needs more attention or because it is a good quality document that integrates the elements of science and communication. Dr. Grifo responded that it was the latter reason. She could not offer an opinion on whether the document is implemented because she has been employed at EPA for only 18 months, but she welcomed any information about instances in which the *Risk Characterization Policy* is not working.