

Message

From: Woodall, George [Woodall.George@epa.gov]
Sent: 5/16/2018 1:21:10 PM
To: Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]; Paul Schlosser
Ex. 6 Ken Bogen [k Ex. 6]
CC: drsg-l@indiana.edu
Subject: RE: [Non-DoD Source] Re: [DRSG] RE: FYI - comment on proposed EPA rule "Strengthening Transparency in Regulatory Science"
Attachments: science.aau0116.full.pd.pdf

Lynn and all,

I am the current President for RASS. I have forwarded my thoughts on to the SOT Council which is repeated below.

The text mentioning RASS is located in Footnote 10 located on Page 18770 (<https://www.gpo.gov/fdsys/pkg/FR-2018-04-30/pdf/2018-09078.pdf>). The language is rather vague, making the statement that "members of the Risk Assessment Specialty Section of the Society of Toxicology", among other organizations, have advocated for open science. The FR Notice also cites the Holmgren Memo from the Obama Administration calling for an Open Data Policy for government agencies, NAS Reports, and both science and science policy position statements from journals.

See also the attached article published in Science and authored by several editors from leading science journals. This article was written in response to the press release (<https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations>) but seems salient in this context as well.

Perhaps the SOT Council should be made aware of this development (if they are not already) and decide if any action is warranted.

Let me further highlight the vagueness of the way both RASS and DRSG have been linked via the phrase "members of" in the footnote. I have no doubt that individuals intimately involved in crafting this proposed rule are a members in one or both groups. Specific mention of RASS and DRSG in this context however, seems to reflect some endorsement of the proposed rule by these groups. It may also be equally valid to say that members of the Church of Latter Day Saints or the Roman Catholic Church have advocated for open science. I concur with forwarding a comment that reference to DRSG in the context of this proposed rule is misleading and should be dropped in any further actions on the rule.

George

George M. Woodall, PhD
Toxicologist
President, Risk Assessment Specialty Section

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Postal Address: US EPA, MD B243-01, Research Triangle Park, NC 27711
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From: Flowers, Lynn [mailto:Flowers.Lynn@epa.gov]

Sent: Wednesday, May 16, 2018 7:52 AM

To: Paul Schlosser <Ex. 6> Ken Bogen { Ex. 6 }

Cc: drsg-l@indiana.edu

Subject: RE: [Non-DoD Source] Re: [DRSG] RE: FYI - comment on proposed EPA rule "Strengthening Transparency in Regulatory Science"

Why don't you submit a comment that simply says that as the DSRG chair, you don't know what they are referring to by the phrase "advocating for open science." Say that this is an open ended statement that can be construed to support all kinds of things and that you prefer to not be cited in the regulation. Of course everyone would be an advocate for open science. The EPA workgroup that would be reviewing the comments could consider the request in revising the proposed regulation. Wonder what RASS/SOT folks think since they are also cited? It is possible (?) that SOT might comment on the proposed regulation on their own.

Just a thought.

Lynn

Lynn Flowers, PhD, DABT
Associate Director for Science
Office of Science Policy/ORD
US EPA
Washington, DC
202-564-6293

From: Paul Schlosser <[redacted] Ex. 6>

Sent: Wednesday, May 16, 2018 7:26 AM

To: Ken Bogen <[redacted] Ex. 6>

Cc: drsg-l@indiana.edu

Subject: Re: [Non-DoD Source] Re: [DRSG] RE: FYI - comment on proposed EPA rule "Strengthening Transparency in Regulatory Science"

Ken,

So you are offering to review the DRSG records for us? There is an archive of minutes on the website. I can look later for any SRA newsletter items I have.

The DRSG did endorse the platform session, 'Why Being Published Is Not Enough' on QA issues with PBPK modeling. It was parlayed into a journal publication, may have discussed data...

Considering that 99% of my DRSG activity is when I am at work, using EPA email, on an EPA computer, the argument that it was as a private citizen is also problematic. We are regularly warned to avoid even the appearance of conflict.

-Paul

On Wed, May 16, 2018, 6:31 AM Ken Bogen <[redacted] Ex. 6> wrote:

Resha,

I do not interpret "actions requested by the DRSG's Officers or that are in the interest of the DRSG" to be equivalent to "on behalf of DRSG" membership. Moreover, once DRSG minutes are reviewed to confirm that DRSG had indeed never adopted any official policy or recommendation as claimed by EPA, a letter from the DRSG Chair or DRSG Exec Committee or DRSG Officers would simply be a correction of a factual error published by EPA concerning DRSG.

The U.S. Supreme Court has ruled that public employee speech involving matters of public concern constitutes protected speech under the First Amendment. Membership per se (not sponsored by or via a government employer) in a scientific organization is a private act taken in relation to scientific matters of public concern. EPA thus cannot lawfully restrict or retaliate against any of its employees simply (as a private citizen in their private capacity) for

being a member of a scientific/professional organization *whose officers* act in good faith to correct that Agency's public misstatement of facts of record concerning that organization. Such a correction cannot meaningfully be construed to constitute political activity or public policy advocacy even by DRSG-letter authors, let alone by any other DRSG member(s).

Ken

Kenneth T. Bogen, Dr.P.H., DABT

Ex. 6

ktbogen.com

On May 15, 2018, at 2:50 PM, Putzrath, Resha M CIV USN NAVMCPUBHLHCEN PORS (US) <resha.m.putzrath.civ@mail.mil> wrote:

Is it within the role of "take other actions requested by the DRSG's Officers or that are in the interest of the DRSG" for the Executive Committee or the Chair to provide comments "on behalf of DRSG" on the draft document EPA submits for public comment? If so, I will have to resign from the specialty section.

Respectfully,
Resha
202 342 2110

-----Original Message-----

From: Ken Bogen [Ex. 6]

Sent: Tuesday, May 15, 2018 2:26 PM

To: Chiu, Weihsueh A

Cc: Roger McClellan; Ries, Divinia (DEQ); drsg-l@indiana.edu; terje.aven@uis.no; macdonell@anl.gov; Putzrath, Resha M CIV USN NAVMCPUBHLHCEN PORS (US); Underwood, Patricia M CIV (US); Walker, Yvonne P CIV USN NAVMCPUBHLHCEN PORS (US)

Subject: Re: [Non-DoD Source] Re: [DRSG] RE: FYI - comment on proposed EPA rule "Strengthening Transparency in Regulatory Science"

Importance: High

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Weihsueh et al.,

My previous email to you included a suggested modification and my offer to be one co-signatory (possibly among others on the DRSG governing Officers) as Past-Chair currently serving as one of DRSG's seven governing officers (i.e., currently serving as a DRSG Trustee and Officer).

I disagree with Rita that your proposed letter (with or without my proposed modification or co-

signature) purports to represent any official SRA response. I also disagree with Rita that DRSG as an SRA specialty group requires any official permission from SRA or from the SRA Board for a letter/comment along the lines you proposed to be sent to EPA. Such a letter would clearly and merely represent the DRSG governing officers' (or perhaps Executive Committee or just Chair) response to an official and inaccurate EPA mischaracterization of purported "policies or positions" taken by DRSG, when in fact no such policies or recommendation exist now or have ever existed since DRSG was created. Such a letter does not represent an official DRSG position or policy, but rather simply corrects an inaccurate, erroneous statement that EPA has published in the Federal Register citing a fictitious DRSG (not SRA) policy/recommendation.

The DRSG by-laws specifically allow the DRSG Executive Committee to "make decisions and recommendations for any other business of the DRSG," and moreover specify that among the duties of the Chair is to "take other actions requested by the DRSG's Officers or that are in the interest of the DRSG" (Caution-http://www.sra.org/sites/default/files/u35/DRSG_by-laws.pdf < Caution-http://www.sra.org/sites/default/files/u35/DRSG_by-laws.pdf >). A DRSG correction of a clearly erroneous public statement made about DRSG, along the lines of your proposed DRSG letter (with or without my proposed modification or co-signature) is thus clearly within the purview of the DRSG Executive Committee/Officers and of your duties as the current DRSG Chair (e.g., perhaps after polling the Executive Committee or all DRSG Officers), according to DRSG by-laws. Such a letter to EPA cannot be misconstrued as a DRSG recommendation or policy (which might require polling the DRSG membership), but rather necessarily and merely represents a public correction of a factually erroneous and misleading statement by EPA about DRSG per se. EPA cannot be allowed to make false statements about DRSG and thereby fabricate official DRSG support for EPA's proposed policies. It is DRSG's responsibility to correct the public record concerning DRSG.

Ken

Kenneth T. Bogen, Dr.P.H., DABT

Current serving DRSG Past-Chair (current DRSG Trustee and Officer, per DRSG by-laws) E

Ex. 6 T 925.639.5940 ktbogen.com < Caution-<https://www.ktbogen.com> >

On May 15, 2018, at 1:32 PM, Putzrath, Resha M CIV USN NAVMCPUBHLHCEN PORS (US) <resha.m.putzrath.civ@mail.mil> < Caution-<mailto:resha.m.putzrath.civ@mail.mil> > > wrote:

I partially concur with Roger. I haven't had time to read the letter, as I am crunching several projects, but I am very concerned with an ad hoc approach to anything appearing official from SRA.

I don't think Weihsueh can send a letter as our chair without at least surveying the membership. He can mention that he was elected chair of our group, but to date, I don't believe any of our past elected officers have "spoken" for the group except within SRA functions. This would be a substantial change in policy.

Whether or not I agree with the letter when I have time to read it, I am very concerned that anyone associates my name with a position that I have not reviewed, much less some subset of people who

happened to have time to read their emails. What about our members who are on vacation or otherwise unavailable to get their emails today? If SRA specialty sections are going to take official positions on government policies, I may have to resign as it could provide a conflict with my employment.

Furthermore, if it is to represent an official position, I would think it needs to be approved by the officers of SRA.

Respectfully,
Resha M. Putzrath, Ph.D., DABT
Navy and Marine Corps Public Health Center Portsmouth, VA

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202-342-2110

-----Original Message-----

From: Roger McClellan Ex. 6
Sent: Tuesday, May 15, 2018 1:03 PM
To: Ries, Divinia (DEQ); Chiu, Weihsueh A; drsg-l@indiana.edu
Cc: terje.aven@uis.no; macdonell@anl.gov; Ken Bogen; Roger McClellan
Subject: [Non-DoD Source] Re: [DRSG] RE: FYI - comment on proposed EPA rule "Strengthening Transparency in Regulatory Science"

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To all:

I concur with having Dr Chiu send the letter with the suggested modifications. I think the letter is appropriate and should be kept short and straightforward. I do NOT think it appropriate to add any other signatures, Dr Chiu is responding in his role as our Chair..

Regards,
Roger McClellan

On Tuesday, May 15, 2018 8:31 AM, "Ries, Divinia (DEQ)" <RIESD@michigan.gov> wrote:

Weihsueh,

Good catch. I agree with your comment.

Thanks,
Divinia

Divinia Nolasco Ries, MPH, MS, Ph.D.
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P.O. Box 30426
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Phone#: 517-284-5142
riesd@michigan.gov <Caution-Caution-mailto:riesd@michigan.gov >
From: Chiu, Weihsueh A <wchiu@cvm.tamu.edu>
Sent: Tuesday, May 15, 2018 10:24 AM
To: drsg-l@indiana.edu
Cc: terje.aven@uis.no; macdonell@anl.gov
Subject: [DRSG] FYI - comment on proposed EPA rule "Strengthening Transparency in Regulatory Science"
Importance: High

Dear DRSG Members,

I am planning on submitting the attached public comment on EPA's proposed rule "Strengthening Transparency in Regulatory Science." Specifically, the Proposed Rule inaccurately suggests that the DRSG has official policies or recommendations on this topic. The comment is simply for EPA to remove reference to the DRSG from the final rule.

Let me know if you have any concerns or comments by the end of the week (Sunday 5/20). Thanks!

Regards,
Weihsueh
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