

To: Yamada, Richard (Yujiro)[yamada.richard@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]
From: Baptist, Erik
Sent: Fri 1/12/2018 1:37:18 PM
Subject: RE: new initiative on making science available.

Let's plan for 10:30 a.m. I will reschedule my conflict.

Erik Baptist

Senior Deputy General Counsel

Office of General Counsel

U.S. Environmental Protection Agency

1200 Pennsylvania Ave., NW

Washington, DC 20460

(202) 564-1689

baptist.erik@epa.gov

From: Yamada, Richard (Yujiro)
Sent: Friday, January 12, 2018 8:10 AM
To: Bolen, Brittany <bolen.brittany@epa.gov>
Cc: Baptist, Erik <Baptist.Erik@epa.gov>
Subject: Re: new initiative on making science available.

I can be there at 10:30 - if plans change I can be flexible - thanks

Sent from my iPhone

On Jan 12, 2018, at 8:06 AM, Bolen, Brittany <bolen.brittany@epa.gov> wrote:

Hey guys, Ryan and I are part of a larger briefing at 10am that can't be rescheduled. I'm also tied up from 9-10 with an OW briefing. Erik, if you cannot make 1030 work then I believe we'll need to have Richard call in for a later time since he is unavailable after 11am. Alternatively, Richard and I can meet with Ryan at 1030 and I can fill you in later today.

Sent from my iPhone

On Jan 11, 2018, at 8:15 PM, Baptist, Erik <Baptist.Erik@epa.gov> wrote:

That works for me.

Erik Baptist

Senior Deputy General Counsel

Office of General Counsel

U.S. Environmental Protection Agency

1200 Pennsylvania Ave., NW

Washington, DC 20460

(202) 564-1689

baptist.erik@epa.gov

From: Yamada, Richard (Yujiro)

Sent: Thursday, January 11, 2018 8:12 PM

To: Baptist, Erik <Baptist.Erik@epa.gov>

Cc: Bolen, Brittany <bolen.brittany@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>

Subject: Re: new initiative on making science available.

Shall we do 10 am? (I have us down for 10:30) Thanks

Sent from my iPhone

On Jan 11, 2018, at 8:10 PM, Baptist, Erik <Baptist.Erik@epa.gov> wrote:

I'm free before 10:30 a.m.

Erik Baptist

Senior Deputy General Counsel
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Yamada, Richard (Yujiro)
Sent: Thursday, January 11, 2018 1:20 PM
To: Bolen, Brittany <bolen.brittany@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>
Cc: Baptist, Erik <Baptist.Erik@epa.gov>
Subject: RE: new initiative on making science available.

11 AM or earlier would be good for me – anytime after that I will have to call in, thanks! Richard

From: Bolen, Brittany
Sent: Thursday, January 11, 2018 1:19 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>
Cc: Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>
Subject: Re: new initiative on making science available.

Sure. What time? 11am, 1pm, or after 3pm tomorrow works best for me, but I can move things around!

On Jan 11, 2018, at 10:05 AM, Jackson, Ryan <jackson.ryan@epa.gov> wrote:

Tomorrow.

From: Bolen, Brittany
Sent: Thursday, January 11, 2018 10:01 AM
To: Jackson, Ryan <jackson.ryan@epa.gov>
Cc: Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>
Subject: Re: new initiative on making science available.

Re: the policy, Richard and I met on this yesterday, and have a path forward. Would you like to discuss later today or tomorrow?

On Jan 11, 2018, at 9:32 AM, Jackson, Ryan <jackson.ryan@epa.gov> wrote:

Ex. 5 - Deliberative Process

Ryan Jackson

Chief of Staff

U.S. Environmental Protection Agency

(202) 564-6999

Gentry, Nathan

From: Gunasekara, Mandy
Sent: Tuesday, January 16, 2018 5:16 PM
To: Ringel, Aaron; Woods, Clint
Cc: Lyons, Troy; Fotouhi, David; Yamada, Richard (Yujiro)
Subject: Re: Circling Back on Administrator Meeting

[REDACTED]

Sent from my iPhone

On Jan 16, 2018, at 2:27 PM, Ringel, Aaron <ringel.aaron@epa.gov> wrote:

All, see below follow up from Chairman Smith's meeting with the administrator. Want to check on who would be most appropriate from them to speak with. In short, this is in regards to his pitch that EPA internally implement the HONEST Act (no regulation can go into effect unless the scientific data is publicly available for review). [REDACTED]

-Aaron

From: Brazauskas, Joseph [<mailto:Joseph.Brazauskas@mail.house.gov>]
Sent: Tuesday, January 16, 2018 1:35 PM
To: Ringel, Aaron <ringel.aaron@epa.gov>
Subject: Circling Back on Administrator Meeting

Aaron,

It was great to see you last week and appreciate the Administrator's time. Chairman Smith is very keen for our staff to get together to discuss further transparent science-based regulations at the EPA. We can meet at your earliest convenience with the appropriate EPA staff to discuss this matter further. When you have identified who is best to handle this matter moving forward please let me know and we can schedule some time to discuss. Hope to hear from you soon. Next week we are not in session so we should have a number of days and times available.

Thank you,
Joe

Joseph A. Brazauskas
Staff Director and Senior Counsel
Subcommittee on Environment
Committee on Science, Space and Technology
Lamar Smith, Chairman
P: (202) 225-6371

Gentry, Nathan

From: Yamada, Richard (Yujiro)
Sent: Tuesday, January 16, 2018 6:10 PM
To: Ringel, Aaron; Lyons, Troy; Fotouhi, David; Gunasekara, Mandy
Subject: RE: Circling Back on Administrator Meeting

[REDACTED]

From: Ringel, Aaron
Sent: Tuesday, January 16, 2018 2:28 PM
To: Lyons, Troy <lyons.troy@epa.gov>; Fotouhi, David <Fotouhi.David@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Subject: FW: Circling Back on Administrator Meeting

All, see below follow up from Chairman Smith's meeting with the administrator. Want to check on who would be most appropriate from them to speak with. In short, this is in regards to his pitch that EPA internally implement the HONEST Act (no regulation can go into effect unless the scientific data is publicly available for review). [REDACTED]

-Aaron

From: Brazauskas, Joseph [<mailto:Joseph.Brazauskas@mail.house.gov>]
Sent: Tuesday, January 16, 2018 1:35 PM
To: Ringel, Aaron <ringel.aaron@epa.gov>
Subject: Circling Back on Administrator Meeting

Aaron,

It was great to see you last week and appreciate the Administrator's time. Chairman Smith is very keen for our staff to get together to discuss further transparent science-based regulations at the EPA. We can meet at your earliest convenience with the appropriate EPA staff to discuss this matter further. When you have identified who is best to handle this matter moving forward please let me know and we can schedule some time to discuss. Hope to hear from you soon. Next week we are not in session so we should have a number of days and times available.

Thank you,
Joe

Joseph A. Brazauskas
Staff Director and Senior Counsel
Subcommittee on Environment
Committee on Science, Space and Technology
Lamar Smith, Chairman
P: (202) 225-6371

To: Ringel, Aaron[ringel.aaron@epa.gov]
Cc: Gomez, Laura[Gomez.Laura@epa.gov]; Yamada, Richard (Yujiro)[yamada.richard@epa.gov];
Bolen, Brittany[bolen.brittany@epa.gov]
From: Schwab, Justin
Sent: Tue 1/23/2018 10:57:33 PM
Subject: Re: Declined: EPA PRE-INTERNAL CALL : HONEST ACT IMPLEMENTATION

Right now I'm free 1-3 or after 4. The GC or the Administrator may always pull me out though. I'll do my best to keep it open if we move to one of those 2 slots.

Sent from my iPhone

> On Jan 23, 2018, at 5:28 PM, Ringel, Aaron <ringel.aaron@epa.gov> wrote:

>

> Can we move this to the afternoon?

>

> Sent from my iPhone

>

>> On Jan 23, 2018, at 4:26 PM, Schwab, Justin <Schwab.Justin@epa.gov> wrote:

>>

>> I'm booked for 2 air briefings with OAR during this time.

>>

>> <meeting.ics>

To: Beck, Nancy[beck.nancy@epa.gov]
Cc: Baptist, Erik[baptist.erik@epa.gov]; Schwab, Justin[schwab.justin@epa.gov]
From: Yamada, Richard (Yujiro)
Sent: Wed 1/31/2018 7:54:14 PM
Subject: RE: For review - Draft EPA Testimony for House Science Hearing

Yes, thanks this is helpful – didn't know about the intricacies of CBI – ok, we will need to thread this one real tight! Thanks Nancy!

From: Beck, Nancy
Sent: Wednesday, January 31, 2018 2:51 PM
To: Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
Subject: RE: For review - Draft EPA Testimony for House Science Hearing

So for pesticide registrations, the regulation (part 158) requires a huge amount of data to be submitted to the agency—it costs companies millions of dollars to do these guideline studies. Guideline studies of this type are never put in journal publications—there is no audience for them. thus in IARC's eyes they are not published. IARC makes no efforts to use or collect them. Which is a major problem as these are very high quality standardized studies.

My understanding is that these studies come in as CBI, but for a large majority of them, the CBI can be waived and the data can be made available (if requested). Making data available is very different than requiring a publication requirement. Such a requirement would be incredibly burdensome, not practical and you would need to create a whole new arm of the publishing industry to publish these types of studies that nobody is interested in. Note these full study reports are often hundreds of pages (they include extremely robust documentation) each. Nobody is interested in publishing these (nor having journal peer review conducted on them).

EPA staff review them as part of the pesticide registration/re-registration process.

This will also be a problem for TSCA where for many existing chemicals (thousands) for the EU registrations, companies conduct OECD guideline studies. Similar to my comments above, the studies get shared with ECHA but there is no incentive for anyone, anywhere, to publish them. It is likely that when we do TSCA risk evaluations, companies will provide us with these studies as CBI (to protect the costs/money they spent to do the testing- it's a competitiveness issue). These

data will be extremely valuable, extremely high quality, and NOT published.

The directive needs to be revised. Without change it will jeopardize our entire pesticide registration/ re-registration review process and likely all TSCA risk evaluations.

Let me know what more you may need from me to facilitate a change.

Thanks,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: 202-731-9910

beck.nancy@epa.gov

From: Yamada, Richard (Yujiro)

Sent: Wednesday, January 31, 2018 2:30 PM

To: Beck, Nancy <Beck.Nancy@epa.gov>

Cc: Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>

Subject: RE: For review - Draft EPA Testimony for House Science Hearing

Ex. 5 - Deliberative Process

To: Yamada, Richard (Yujiro)[yamada.richard@epa.gov]; Schwab, Justin[Schwab.Justin@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]
Cc: Baptist, Erik[Baptist.Erik@epa.gov]
From: Beck, Nancy
Sent: Sat 2/3/2018 5:43:39 PM
Subject: OPP data sharing practices
OPP Data Requirements2-2-18.docx

Attached is a backgrounder on how we use/protect proprietary data in our pesticides program. I thought this may be useful as you work on a broader data-sharing policies for the agency.

Similarly, if you think a similar type of document would be useful coming from our TSCA program, we can put that together as well.

Happy to answer any questions that this document raises.

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

P: 202-564-1273

M: 202-731-9910

beck.nancy@epa.gov

Nancy

How the Office of Pesticide Programs (OPP) Obtains and Protects Proprietary Data Used to Support Pesticide Regulatory Decisions

Background

- The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to register pesticides, conduct registration review of pesticides, and require supporting studies, as stipulated under 40 Code of Federal Regulations (CFR) Part 158, to meet statutory safety standards.
- Studies in Part 158 provide the scientific basis for characterizing the potential human health and environmental risks associated with pesticide exposure
- Includes flexibility, as additional data can be required (§158.75), alternative approaches can be accepted, and studies can be waived (§158.45)
- FIFRA Sections 10 & 3 provide data protections and exclusivity provisions that incentivize research and development of new, reduced risk chemistries and ensure that growers have tools to combat emerging pest pressures and pesticide resistance.

Costs of New Active Ingredient Registration

- In 2016, industry stakeholders estimated that from molecule discovery through registration, it costs nearly \$300 million and takes 11 years of research and development to bring a new pesticide product to the market.
- The costs of data development specific to pesticide registration vary based on the use pattern, but OPP estimates that the full suite of Part 158 data costs over \$12 million for a first food use of conventional pesticide.

FIFRA Section 10 Data Protections

- Congress granted data protection rights to entities that develop and submit data in support of registration decisions; however, OPP makes its reviews of this data publically available.
- While some data is protected Confidential Business Information (CBI)¹, most of the data used in OPP risk assessments (e.g., Part 158 data, open literature data, efficacy data) does not include this type of information and thus is not considered CBI.
- Examples of information submitted as part of the regulatory process for pesticides may qualify as CBI include:
 - Identity of inert ingredient(s) in the product and ingredient sources
 - Description of manufacturing processes
 - Product chemistry registration data
- Even if data is not considered CBI, FIFRA Section 10(g) protects registrants of pesticides in the United States against unauthorized use of their proprietary health and safety data by competitors to obtain pesticide registrations in foreign countries.
 - If a request for data is submitted under the Freedom of Information Act (FOIA), the requestor must sign an Affidavit of Non-Multinational Status to affirm that he or she does not intend to, and will not purposefully or negligently deliver (or cause delivery of) the information to a foreign or multinational pesticide producer.
- FIFRA Section 10 protections would no longer be guaranteed if all registrant-owned data was made publically available.

¹ <https://www.epa.gov/foia/limitations-disclosure-information-under-pesticide-law>

FIFRA Section 3 Data Compensation and Exclusive Use²

- Other registrants that wish to rely on data owned and generated by a pesticide registrant are obligated to offer financial compensation to the data submitter for the right to rely on the data to support their own registration.
 - Data compensation only grants the requestor the right to cite the data for EPA registration, it does not grant the requestor access to the cited data.
 - Studies are generally compensable for a period of 15 years from the date of submission to EPA
- Exclusive Use -- similar to other patent higher form of protection that gives the data submitter the right to refuse permission for the Agency to rely on its data in support of another entity's registration for 10 years
 - Only applies to data submitted to support the first registration for an active ingredient
 - Can be extended up to 3 years based on minor use registrations

Non-Proprietary Data Sources

- Other information beyond the 40CFR §158.45 data requirements is often considered during registration review (e.g., open literature data, epidemiological data, incident data, international assessments)
 - OPP has transparent and systematic criteria for determining the acceptability/usability of data from these sources³
- In some cases, OPP works with the Office of Research and Development (ORD) to develop necessary data outside the universe of available data
 - Examples: dust exposure data, pyrethroid acute toxicity studies
 - OPP does not have a role in ORD's selection of research grants recipients
 - Selection by ORD does not mean data generated by grant recipients meets OPP's criteria for risk assessment purposes

² <https://www.epa.gov/pesticide-registration/guidance-data-compensation>

³ <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-selecting-and-evaluating-open>

To: Bolen, Brittany[bolen.brittany@epa.gov]
Cc: Feeley, Drew (Robert)[Feeley.Drew@epa.gov]; Woods, Clint[woods.clint@epa.gov]; Schwab, Justin[Schwab.Justin@epa.gov]; Baptist, Erik[Baptist.Erik@epa.gov]; Beck, Nancy[Beck.Nancy@epa.gov]
From: Yamada, Richard (Yujiro)
Sent: Thur 2/8/2018 6:44:48 PM
Subject: Re: latest version

Yes - this is latest version - I'm still working on the issue of third party data - thanks

Sent from my iPhone

On Feb 8, 2018, at 10:26 AM, Bolen, Brittany <bolen.brittany@epa.gov> wrote:

Richard – following up on Monday’s morning meeting, is this the most recent version?

Thanks,

Brittany

From: Yamada, Richard (Yujiro)
Sent: Monday, January 29, 2018 5:58 PM
To: Feeley, Drew (Robert) <Feeley.Drew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Woods, Clint <woods.clint@epa.gov>
Cc: Schwab, Justin <Schwab.Justin@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: latest version

(This email contains deliberative and pre-decisional information)

Here’s the latest version – no longer outline, but has more “substance” to it – thanks much,
Richard

Ps: Adding Nancy to the convo – sorry Nancy, this is still rough, and I know issues of CBI need to be more thoroughly addressed

Richard Yamada

Deputy Assistant Administrator

Office of Research and Developm

U.S. Environmental Protection A

Phone: 202-564-1727

yamada.richard@epa.gov

Richard
added
Nancy
b/c of CBI
issues for
pau employees
raised last year

To: Beck, Nancy[beck.nancy@epa.gov]; Woods, Clint[woods.Clint@epa.gov]
Cc: Schwab, Justin[schwab.justin@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]; Feeley, Drew (Robert)[Feeley.Drew@epa.gov]; Jackson, Ryan[jackson.ryan@epa.gov]
From: Yamada, Richard (Yujiro)
Sent: Thur 2/15/2018 11:12:50 PM
Subject: latest version
[data access memo V4.docx](#)

(this email contains deliberative and pre-decisional information)

Hi Guys,

Here is the latest version with my edits, including earlier comments by Clint and Nancy. Thanks for your patience – it's been an unusually busy week.

I tried to understand and comment on both Clint and Nancy's comments – in most cases I was able to address. These are some tough issues, with a lot of exclusionary cases.

Here's a suggested timeline and schedule:

1. Nancy and Clint Review
2. Policy Office Review (Drew/Brittany)
3. OGC Review (Justin)
4. Share with Career Staff (OGC/ORD/etc)
5. Additional edits and comments by team
6. Brief the Administrator

Thanks much,

Richard

Richard Yamada

Deputy Assistant Administrator

Office of Research and Development

U.S. Environmental Protection Agency

Phone: 202-564-1727

yamada.richard@epa.gov

To: Bolen, Brittany[bolen.brittany@epa.gov]
Cc: Feeley, Drew (Robert)[Feeley.Drew@epa.gov]; Woods, Clint[woods.clint@epa.gov]; Schwab, Justin[Schwab.Justin@epa.gov]; Baptist, Erik[Baptist.Erik@epa.gov]; Beck, Nancy[Beck.Nancy@epa.gov]
From: Yamada, Richard (Yujiro)
Sent: Mon 2/12/2018 4:07:21 PM
Subject: Re: latest version

I can be available for call tomorrow or Weds - let me know what time works - thanks

Sent from my iPhone

On Feb 12, 2018, at 11:04 AM, Bolen, Brittany <bolen.brittany@epa.gov> wrote:

Hi - Can we please schedule a planning meeting/call on this tomorrow or Wednesday? The administrator asked about it on Friday and RJ asked to have this rolled out by end of the month.

From: Yamada, Richard (Yujiro)
Sent: Thursday, February 8, 2018 1:45 PM
To: Bolen, Brittany <bolen.brittany@epa.gov>
Cc: Feeley, Drew (Robert) <Feeley.Drew@epa.gov>; Woods, Clint <woods.clint@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: Re: latest version

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Sent from my iPhone

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Thanks,

Brittany

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Sent: Monday, January 29, 2018 5:58 PM
To: Feeley, Drew (Robert) <Feeley.Drew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Woods, Clint <woods.clint@epa.gov>
Cc: Schwab, Justin <Schwab.Justin@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: latest version

(This email contains deliberative and pre-decisional information)

Here's the latest version – no longer outline, but has more “substance” to it – thanks much, Richard

Ps: Adding Nancy to the convo – sorry Nancy, this is still rough, and I know issues of CBI need to be more thoroughly addressed

Richard Yamada

Deputy Assistant Administrator

Office of Research and Development

U.S. Environmental Protection Agency

Phone: 202-564-1727

yamada.richard@epa.gov

To: Yamada, Richard (Yujiro)[yamada.richard@epa.gov]; Jackson, Ryan[jackson.ryan@epa.gov]
Cc: Woods, Clint[woods.clint@epa.gov]; Feeley, Drew (Robert)[Feeley.Drew@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]
From: Beck, Nancy
Sent: Wed 2/21/2018 7:40:41 PM
Subject: RE: latest version

I'm at OMB til 3:30 then have a CEQ meeting at 4:30-5:30 so I was just going to stay over there. Perhaps I can find a spot to dial in or can do it at 6pm tomorrow...

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: 202-731-9910

beck.nancy@epa.gov

From: Yamada, Richard (Yujiro)
Sent: Wednesday, February 21, 2018 2:29 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>
Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Woods, Clint <woods.clint@epa.gov>; Feeley, Drew (Robert) <Feeley.Drew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>
Subject: Re: latest version

How about tomorrow afternoon between 4 to 6? I know Clint will have to call in and I know Nancy is swamped - thanks much, Richard

Sent from my iPhone

On Feb 21, 2018, at 2:26 PM, Jackson, Ryan <jackson.ryan@epa.gov> wrote:

Thank you all for this. Can we meet about this this week?

From: Yamada, Richard (Yujiro)
Sent: Wednesday, February 21, 2018 1:10 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>
Subject: Fwd: latest version

Please see attached - apologies for slight delay

Sent from my iPhone

Begin forwarded message:

From: "Feeley, Drew (Robert)" <Feeley.Drew@epa.gov>
Date: February 21, 2018 at 1:05:57 PM EST
To: "Yamada, Richard (Yujiro)" <yamada.richard@epa.gov>
Cc: "Bolen, Brittany" <bolen.brittany@epa.gov>
Subject: RE: latest version

Hi Richard – Per our call, attached is the most recent draft of the directive. It is a cleaned up version that is easier to read. If you want the one with track changes for reference, I can send that too, but it's hard to read. Generally, I tried to remove some of the duplicative language and reinforce consistency. I also made comments that are best left to you/Nancy/Clint to address. I plan to continue working on the draft this afternoon – primarily the first part, before the principles.

From: Yamada, Richard (Yujiro)
Sent: Tuesday, February 20, 2018 10:37 PM
To: Feeley, Drew (Robert) <Feeley.Drew@epa.gov>
Cc: Bolen, Brittany <bolen.brittany@epa.gov>
Subject: Fwd: latest version

Hey Drew - can u work ur magic and get this back to us, so that I can send to Justin?
Thanks much, Richard

Sent from my iPhone

Begin forwarded message:

From: "Beck, Nancy" <Beck.Nancy@epa.gov>

Date: February 20, 2018 at 9:24:58 PM EST
To: "Woods, Clint" <woods.clint@epa.gov>, "Yamada, Richard (Yujiro)" <yamada.richard@epa.gov>
Subject: RE: latest version

A few additional suggestions from me. Thanks Richard!

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: [202-564-1273](tel:202-564-1273)
M: [202-731-9910](tel:202-731-9910)
Beck.Nancy@epa.gov

From: Woods, Clint
Sent: Tuesday, February 20, 2018 7:21 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Subject: RE: latest version

A few minor adjustments from me – Thanks!

From: Beck, Nancy
Sent: Tuesday, February 20, 2018 7:07 PM
To: Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Woods, Clint <woods.clint@epa.gov>
Subject: RE: latest version

Thanks!

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: 202-731-9910

beck.nancy@epa.gov

From: Yamada, Richard (Yujiro)
Sent: Tuesday, February 20, 2018 7:06 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Woods, Clint <woods.clint@epa.gov>
Subject: Re: latest version

I believe this is latest - thanks

<https://www.congress.gov/115/bills/hr1430/BILLS-115hr1430rfs.pdf>

Sent from my iPhone

On Feb 20, 2018, at 6:48 PM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

Do either of you have the most recent version of the secret science bill?

Thanks.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: 202-731-9910

To: Yamada, Richard (Yujiro)[yamada.richard@epa.gov]; Feeley, Drew (Robert)[Feeley.Drew@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]; Woods, Clint[woods.clint@epa.gov]
From: Beck, Nancy
Sent: Fri 2/23/2018 12:30:49 AM
Subject: exemptions/waivers

From the OMB peer review bulletin:

https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/fedreg/2005/011405_pccr.pdf

you may need to tweak but hopefully there is something helpful here that can be borrowed/adopted

“Agencies need not have peer review conducted on information that is: 1. Related to certain national security, foreign affairs, or negotiations involving international trade or treaties where compliance with this Bulletin would interfere with the need for secrecy or promptness;”

A health or safety dissemination where the agency determines that the dissemination is time-sensitive (e.g., findings based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began);

Section VIII also allows for a deferral or waiver of the requirements of the Bulletin where necessary. Specifically, the agency head may waive or defer some or all of the peer review requirements of Sections II or III of this Bulletin if there is a compelling rationale for waiver or deferral. Waivers will seldom be warranted under this provision because the Bulletin already provides significant safety valves, such as: The exemptions provided in Section IX, including the exemption for timesensitive health and safety information; the authorization for alternative procedures in Section IV; and the overall flexibility provided for peer reviews of influential scientific information under Section II. Nonetheless, we have included this waiver and deferral provision to ensure needed flexibility in unusual and compelling situations not otherwise covered by the exemptions to the Bulletin, such as situations where unavoidable legal deadlines prevent full compliance with the Bulletin before information is disseminated. Deadlines found in consent decrees agreed to by agencies after the Bulletin is issued will not ordinarily warrant waiver of the Bulletin’s requirements because those deadlines should be negotiated to permit time for all required procedures, including peer review. In addition, when an agency is unavoidably up



against a deadline, deferral of some or all requirements of the Bulletin (as opposed to outright waiver of all of them) is the most appropriate accommodation between the need to satisfy immovable deadlines and the need to undertake proper peer review.

Deferral and Waiver: The agency head may waive or defer some or all of the peer review requirements of Sections II and III of this Bulletin where warranted by a compelling rationale. If the agency head defers the peer review requirements prior to dissemination, peer review shall be conducted as soon as practicable.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

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To: Schwab, Justin[schwab.justin@epa.gov]; Leopold, Matt[Leopold.Matt@epa.gov]
Cc: Jackson, Ryan[jackson.ryan@epa.gov]; Woods, Clint[woods.Clint@epa.gov]; Beck, Nancy[beck.nancy@epa.gov]; Feeley, Drew (Robert)[Feeley.Drew@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]
From: Yamada, Richard (Yujiro)
Sent: Fri 2/23/2018 9:54:08 PM
Subject: DRAFT - email contains deliberative and pre-decisional info
[data access memo V7.docx](#)

(THIS EMAIL CONTAINS DELIBERATIVE AND PRE-DECISIONAL INFO)

Matt and Justin,

Please see attached draft for the memo -- I have left in place some comments since it reflects some issues that we wanted to flag for you. When you share with your legal team, you may want to eliminate the comments on the side.

Ryan -- the e-clearance platform is a few hundred thousand dollars - less than \$1 M. I will get you a better number early next week.

Thank you and best,

Richard

Richard Yamada

Deputy Assistant Administrator

Office of Research and Development

U.S. Environmental Protection Agency

To: Schwab, Justin[Schwab.Justin@epa.gov]; Yamada, Richard (Yujiro)[yamada.richard@epa.gov]
Cc: Bolen, Brittany[bolen.brittany@epa.gov]; Jackson, Ryan[jackson.ryan@epa.gov]; Feeley, Drew (Robert)[Feeley.Drew@epa.gov]; Woods, Clint[woods.clint@epa.gov]; Bowman, Liz[Bowman.Liz@epa.gov]; Bennett, Tate[Bennett.Tate@epa.gov]; Lyons, Troy[lyons.troy@epa.gov]; Bolen, Derrick[bolen.derrick@epa.gov]
From: Beck, Nancy
Sent: Mon 3/5/2018 1:42:01 AM
Subject: RE: new directive - meeting?

I'm also happy to discuss. Derrick Bolen can help w/ my schedule.

Also, FYI, the paragraph below appears in some documents our pesticides program released in December 2016. I happened to be reading them this weekend and was not previously aware of the statements.

I'm sharing for awareness, particularly regarding court cases that are cited.

Nancy

“To be clear, EPA continues to believe that the raw data should be made available for public

inspection to ensure that EPA's assessments are as transparent as possible. While the EPA

therefore strives to ensure that data underlying research it relies upon are accessible to the

extent possible, it does not believe that it is appropriate to refuse to consider published studies in the absence of underlying data. The EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data

and the federal courts (see *Coalition of Battery Recyclers Association v. EPA*, 604 F.3d 613

(D.C. Cir. 2010); *American Trucking Associations v. EPA*, 203 F.3d 355 (D.C. Cir. 2002)) have

made clear that the EPA is not required to obtain or analyze the raw data in order to rely

on

such studies. If the EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.”

Nancy B. Beck, Ph.D., DABT
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Beck.Nancy@epa.gov

From: Schwab, Justin
Sent: Sunday, March 4, 2018 4:00 PM
To: Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Bolen, Brittany <bolen.brittany@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>; Feeley, Drew (Robert) <Feeley.Drew@epa.gov>; Woods, Clint <woods.clint@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>
Subject: Re: new directive - meeting?

Great. All who want in, please let me know who we should contact to schedule time with you this coming week.

Sent from my iPhone

On Mar 4, 2018, at 3:14 PM, Yamada, Richard (Yujiro) <yamada.richard@epa.gov> wrote:

Justin,

I think this would be a great idea to meet - I'm adding Clint, Drew, Ryan and Liz to this email chain. I will be looking over soon - thanks much,

Richard

Tate and Troy - I've added you for situational awareness.

Sent from my iPad

On Mar 4, 2018, at 12:00 PM, Schwab, Justin <Schwab.Justin@epa.gov> wrote:

Dear All,

1. Carol Ann and I would be happy to (and I think it's a good idea) sit down with the 3 of you in particular early next week to discuss our pass-back and any questions about it you may have.
2. Also, we want to help as much as we can with whatever rollout materials we're drafting, as with the previous directive.
3. FYI, I will be in RTP all day Thursday 3/8, but will give as much as my time as possible over the rest of the week to bringing this home.

Best,

Justin

