Sarah G. Davis - Re: Fwd: Testing the Roadmap - workshop being organized by Dr. Karen Hokanson

From: Sarah G. Davis
To: Tibelius, Christine
Date: 2015-10-27 1:09 PM
Subject: Re: Fwd: Testing the Roadmap - workshop being organized by Dr. Karen Hokanson

Hi Christine,

Sounds great. Phil is the resident expert on all things Road Map related, so I've set-up a meeting between the three of us so he can fill us in.

Related to your note below, I'd be very interested in two topics related to PBRA's budget:

1. Is some of PBRA's $42,500 budget being re-distributed to Rob's team? I remember you mentioning this was a possibility, but I'm not sure what decision arose.
2. Has there been any discussion about Dylan's future? As a reminder, his terms expires Given November is just around the corner, I thought it might be useful to touch base on that front.

Incidentally, France and I will be meeting later this week to make sure our budget tracking aligns.

Thank-you!
Sarah

>>> Christine Tibelius 2015-10-27 11:35 AM >>>
Hi Sarah,

I'd like to have a bit more background on the Roadmap. On the budget side, France and I are meeting this week to see where things sit for the Division in terms of where we are with expenditures and commitments.

Christine

>>> Sarah G. Davis 2015/10/27 10:59 AM >>>
Good morning,

Please see email below.

Phil, as a major dissenting voice in the development of the Road Map, do you think my participation in this activity would be of value? Your honest opinion is appreciated! :)

Christine, obviously this workshop isn't on the event plan nor in my current budget, so perhaps we could chat about whether it would be feasible for me to attend, provided Phil advocates for it. It's being held in Washington, so presumably it would cost approximately $2000. A lot of PBRA travel is happening this fall, so I should have a better snapshot of my budget once those activities are completed.

Sarah

>>> 2015-10-27 8:15 AM >>>

Hi Sarah,

I hope that things are well in Ottawa. I wanted to make an introduction and invite you to a workshop that is being organized for the first week of February next year. The workshop is an attempt to have experienced risk assessors review the Road Map produced by the AHTEG under the Cartagena Protocol in order to provide their feedback. The activity is being funded by a grant from USDA's Biotechnology Risk Assessment Research Grants (BRAG) program, and the award is being managed by (copied here) at the University of Minnesota.

Although it is not an ILSI supported activity, we will be providing meeting space at our offices in Washington as a public service and has asked if I would help out a bit with the organization of the workshop and by extending some informal invitations (like this one). So, let me know if this is something you would be willing and able to participate in. As the National Manager for the PBRA unit your participation would be of tremendous benefit for the activity, and I think your ability to function well in the context of a group discussions will be a big asset as well.

If you have any questions let me know. I'm sure would also be happy to provide any additional details you need regarding the workshop.

Best,

Center for Environmental Risk Assessment
&
Center for Safety Assessment of Food and Feed
ILSI Research Foundation
tel: 202-659-3306 ext.

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From: Philip Macdonald
To: Sarah G. Davis
Date: 2015-11-12 3:50 PM
Subject: Fwd: Re: FW: GIC Risk Assessment Workgroup: Summary of 4 November 2015 Conference Call
Attachments: CPB RA Meeting Concept Note.docx

fyi

>>> 2015-11-12 1:02 PM >>>
Hi

Thanks for sending this. These look like good points to me.

Just as an update for all of you, plans are still in progress for a meeting in February, where our 'experienced' risk assessors who have expressed concern regarding the roadmap and the need for 'technical consensus' (as put it) can have a discussion and develop some recommendations. I think everyone on this message is aware of this meeting. The latest version of the Concept Note is attached. It is now scheduled for the first week in February (in DC).

We are viewing this meeting in February as an opportunity to at least reach some consensus from among the 'like-minded' group of experienced regulators about where the roadmap captures what IS commonly found in 'actual' cases of risk assessment, and where it truly delves into the 'fairy tale' realm, or where it varies by country.

Of course, it will be necessary to take stock after the face-to-face meeting of the AHTEG next week of what changes have been incorporated (if any) into the roadmap, so we can take that into consideration during our February discussion.

There are only two people on the 'to be confirmed' list for the February meeting who are currently members (from parties) on the AHTEG: from South Africa and from Japan. Neither of these have been officially invited to the meeting yet (although knows about it). We have decided it will be better to engage these two more fully after the AHTEG meeting.

I don't necessarily want to keep the February meeting a secret from and the rest of the AHTEG, but I also don't want to give them any impression that they can participate. So, I don't plan to offer it as a way forward or to present anything about it while we are there next week. I hope you agree.

Having said that, I do hope that those of us on this message can find a time to talk about the February meeting while we are together, especially toward the end of next week, so we can think about any changes to our approach based on what is discussed at this AHTEG meeting. (Come to think of it - there should be plenty of down time when we are banned from the AHTEG meeting, if it is anything like the last one in Bonn.)

Phil, we have also been in touch with Sarah Davies about participating. Do not know if you know this.
and

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we have been in touch with [redacted] and he is interested, but he did indicate that he might send you, if he can not attend. Not sure if he communicated this to you.

Let me know your thoughts.

Thanks,

On Thu, Nov 12, 2015 at 10:28 AM, [redacted] > wrote:

> FYI - the following are some talking point I developed on the subject of
> advancing work on additional guidance. Please let me know what you think
> of them.
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> Thanks,
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> Ubi caritas, ibi iustitia.
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>
> *From:*
> *Sent:* Wednesday, November 11, 2015 2:19 PM
> *To:*
> *Cc:*
> *Subject:* RE: GIC Risk Assessment Workgroup: Summary of 4 November 2015
> Conference Call
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> Talking points:

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> Many AHTEG members and participants in the on-line forum have consistently
> stated that work on additional guidance is premature until a final roadmap
> is welcomed by the MOP. Building additional guidance based on draft text
> is inappropriate and creates an unwelcome diversion to finishing the
> roadmap.
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> Many members of the AHTEG are deeply concerned about the process used in
> the open-ended forum. The texts produced and discussed are the outcome of
> a negotiation rather than a consensus among technical experts. As such,
> the process can only produce "chair's text" representing a compromise as
> understood by the chair of the AHTEG.
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> We strongly urge that the process led by the Secretariat seek technical
> consensus on the roadmap first; and only thereafter undertake work to
> extend the principles within the roadmap to guidance as prioritized in
> other conversations.
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CONCEPT NOTE

Meeting to Review the Process for Risk Assessment under the Cartagena Protocol for Biosafety

Based on their experience with risk assessment and approvals of GM crops, participants are invited to a small, focused meeting to evaluate and discuss the 'Roadmap' that has been developed as part of the 'Guidance on Risk Assessment' under the Cartagena Protocol for Biosafety.

This meeting will address the concern that has been expressed by a number of participants (parties and nonparties) during the discussions on Risk Assessment and Risk Management, in the online forum and at MOPs 6 & 7, that the Guidance is not useful in its current form because it goes beyond what is commonly considered in actual cases of risk assessment. The purpose of this exercise is to develop recommendations for the guidance document based on a comparison of common experiences with multiple, actual cases of risk assessment.

PARTICIPANTS:

Participants from countries with experience based on approvals of multiple cases of risk assessment, and who have expressed concern over the usefulness of the roadmap, will participate in this discussion.

Currently, the following countries and tentative participants from each country include:

Argentina: ANBio
Australia: OGTR
Brazil: CTNBio (To be confirmed)
Canada: Sarah Davies / Phil Macdonald, CFIA
Columbia: Instituto Colombiano Agropecuario (To be confirmed)
European Union: EFSA (To be confirmed)
European Union: RIVM GMO Office
Japan: NITE (To be confirmed)
Mexico: CIBIOGEM
Paraguay: MAG (To be confirmed)
Philippines: DOST Biosafety Committee
South Africa: DEA / DAFF (To be confirmed)
USA: (USDA/APHIS)
USA: EPA (To be confirmed)

STEERING COMMITTEE:

, University of Minnesota, US (Chair)
USDA/FAS, US
, Estel Consult, UK
ILSI/CERA, US
, PRRI/Univ. Ghent/Univ. Brussels, Belgium
ABNE, Burkina Faso

METHOD:

In order to structure the discussion, participants are asked to complete an evaluation of the Roadmap based on a risk assessment case study of their choice, one that represents the most current process for risk assessment from their country.

To facilitate this evaluation, the following documents are attached:
1) The most recent draft of the Roadmap (Part I of the 'Guidance on Risk Assessment of Living Modified Organisms').
2) Table 1 which lists every point described in the roadmap, and a column at the end which can be filled in with an evaluation for each point as it is addressed (or not) in the case study.
3) Table 2 which includes four columns representing examples of evaluations of each point from the roadmap in Table 1, from risk assessments found on the BCH for Canada, Brazil, Argentina, and Japan of a specific case (MIR162 maize). The last column in Table 2 provides a summary of common elements across the four countries for each point of the Roadmap.

Participants will conduct this evaluation and provide their results to the meeting organizers 2 weeks before the meeting takes place. The meeting organizers will summarize this information to use as a focus for the discussion.

During the meeting, participants will present their individual evaluation, noting especially those points in the 'Roadmap' which were difficult to interpret as part of their risk assessment.

OUTCOMES:
The expected outcomes of this discussion will be:

1) a clear indication of where the Guidance (the Roadmap, specifically) reflects what is commonly found in 'actual cases' of risk assessments, and where it does not, or where this varies between cases
2) recommendations for how this information could be used to 'revise/improve' the Guidance
3) 'examples' from actual cases of risk assessment to support the recommendations.

Participants will agree on the best routes to disseminate these outcomes, possibly as a report to the Secretariat, and/or in a side-event at MOP8, and/or as a published manuscript.

MEETING DATE/LOCATION:
The proposed dates for the 2.5 day meeting are Feb 1-5, 2016

The meeting will take place in Washington DC.

Travel support is available for participants, as needed.
(*A competitive grant has been awarded by USDA/NIFA to University of Minnesota, in support of this meeting.)*

This conference is being organized by the Stakman Borlaug Center for Sustainable Plant Health of the University of Minnesota, with support from USDA National Institute for Food and Agriculture Biotechnology Risk Assessment Grant Program.