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 IARCs 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

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From: Yamada, Richard (Yujiro)
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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