

AR226-1682

From: Bernard J Reilly on 10/07/2001 09:55 AM
To: Martha L Rees/AE/DuPont@DuPont, Andrea V Malinowski/AE/DuPont@DuPont
cc:
Subject: Environ Monograph

----- Forwarded by Bernard J Reilly/AE/DuPont on 10/07/2001 09:55 AM -----

From: Bernard J Reilly on 10/07/2001 08:47 AM
To: Steve Washburn <SWashburn> cc: Robert Harris <RHarris>, John R Bowman, Joseph Rodricks <JRodricks>, Annette
Subject: Environ Monograph ☐

Steve,

Since we now find we are unable to schedule a meeting with EPA Region 3 next week, then the end of next week for the PFOA monograph summary is fine.

As to the summary, ideally it is short (single digit pages?) but with enough data and analysis and to assure a regulatory official that levels of PFOA significantly above the DuPont CEG of 1 ppb in drinking water do not present an emergency situation requiring an "Safe Drinking Water Act" order to provide alternative drinking water, even if there also is exposure to PFOA in ambient air (Dr Staats on our call last week seemed determined to assign a large dose to air since that route of exposure is more difficult to deal with (e.g. she said it might require the public to wear "gas masks"), of course she is aware of the recent dispersion modeling from the plant).

I assume that your extrapolations from lab animals to man involve calculating an acceptable "daily dose" from all routes of exposure. If that is clear in the summary then you can make whatever split between air and water that is the general practice to turn a dose into a concentration in water and air, that would give us enough background to engage a debate with EPA or the WVDEP if they want to assume air or water the larger source.

-Bernie

Section 1431(a) of Safe Drinking Water Act authorizes the EPA Administrator to take action necessary, to include ordering alternative drinking water, to protect the public's health from an imminent and substantial endangerment created by contaminants in a public water system or an underground source of drinking water. In *US v Price*, the 3rd Circuit ruled "imminent and substantial endangerment" authorizes the issuance of injunctions when there is but a "risk of harm", a more lenient standard than the traditional requirement of threatened irreparable harm. However, the House Report on the SDWA states the emergency authority not to be used in cases "where the risk of harm is remote in time, completely speculative in nature, or *de minimis* in degree." Further, action by the EPA is only authorized when state and local authorities have not acted first. We may use that provision to press EPA to defer to the WVDEP or WVDHHR. However, on our last call Dr. Staats, while agreeing that peroxisome proliferation is not a risk driver for human health, did seem to feel that 1 ppb in drinking water was justified as an action level.

Steve Washburn <SWashburn@environcorp.com> on 10/06/2001 02:53:28 PM



Steve Washburn <SWashburn@environcorp.com> on 10/06/2001 02:53:28 PM

To: REILL2BJ cc: Robert Harris <RHarris>, BOWMA2JR, Joseph Rodricks <JRodricks>, Annette Shipp <AShipp>, Janet Keeler <jkeeler>

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Subject: RE: Environ Input

Bernie -

I am currently planning to get a draft summary of the monograph for you by the end of next week, since the primary author of the monograph (Janet Kester) is out until 10/10. Let me know if you think that you will need something earlier in the week.

I received the good news this morning from John Bowman that 3M will allow Joe Podricks to review and provide input on the monograph, and I have already forwarded a copy to Joe. In Janet's absence, I am also working with one of ENVIRON's lead toxicologists, Annette Shipp, to resolve any outstanding issues on the draft monograph. Joe, Annette, and I are planning to talk on Monday, and discuss how to best summarize the results of the monograph.

Do you have an idea of what level of detail you would like to see in the summary, or how long you would like it to be? At this point, based on our communications, I am assuming that the primary focus would be on presenting our basis for a higher drinking water advisory level, including identification of the key studies and a discussion of the appropriate uncertainty factors to apply in relating the results of those studies to establishing protective levels of exposure for the general population.

Steve

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

From: Bernard J Reilly (mailto:Bernard.J.Reilly@USA.dupont.com)
Sent: Saturday, October 06, 2001 11:03 AM
To: Steve Washburn
Cc: Bernard J Reilly; Robert Harris; Cyndi Migliaccio; John R Bowman;
Andrea V Malinowski; M. Ann Bradley; Paula L Durst; David M Rurak;
Gerald L Kennedy; Isidoros J Zanikos; Martha L Rees; Robert F Pinchot
Subject: Environ Input

Steve,

As you know, we have an urgent need to open the minds of EPA and the WDEP about the extremely conservative nature of our CEG. It must not be used to trigger a mandate for drinking water -- we may obtain much larger concentrations in drinking water from the new test protocol.

We have decided we will not need anyone from Environ at the first meeting with the regulators, but will need at least a summary of your findings. We tried to set up a meeting next week on this but have failed so far, and not sure we will get a meeting week of Oct 15. Indeed I now have a voicemail asking we put our concerns in a writing before any meeting, that would be highly unsatisfactory it seems to us. I will keep you posted, hoping you can get us maybe a draft summary of the monograph in the near future.

--Bernie

Steve Washburn <SWashburn@environcorp.com> on 10/05/2001 12:56:35 PM

To: REILL2BJ
cc: Robert Harris <RHarris@environcorp.com>
Cyndi Migliaccio <CMigliaccio@environcorp.com>

Subject: RE: EPA Region 3 Cannot Meet Next Week

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Bernie -

I am checking with the primary author (Janet Kester) and internal reviewer (Annette Shipp) of the Monograph to ascertain their availability on the dates you indicated in your email. Bob and I are both out of the office and unavailable on October 17, 18, and 19, but it may not be essential for us to be at the meeting with Region III if Janet and/or Annette can attend. Bob and I would both be available on the 24th and probably also on the 22nd.
Steve

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

From: Bernard J Reilly (mailto:Bernard.J.Reilly@USA.dupont.com)
Sent: Thursday, October 04, 2001 7:04 PM
To: swashburn@environcorp.com; charrisd@environcorp.com
Subject: EPA Region 3 Cannot Meet Next Week

----- Forwarded by Bernard J Reilly/AE/DuPont on 10/04/2001 07:03 PM -----

From: Bernard J Reilly on 10/04/2001 07:02 PM
To: David M Rurak/AE/DuPont@DuPont
Robert F Pinchot/DEV/AE/DuPont@DuPont
M. Ann Bradley/STB/DUP@DUP
Robert L Ritchey/CL/DuPont@DuPont
Gerald L Kennedy/AE/DuPont@DuPont
Andrew S Hartten/AE/DuPont@DuPont
Isidoros J Zanikos/AE/DuPont@DuPont
cc: Martha L Rees/AE/DuPont@DuPont
John R Bowman/AE/DuPont@DuPont

Subject: EPA Region 3 Cannot Meet Next Week

I finally linked up late today with Janet Sharke, counsel for EPA Region 3 with our urgent request to meet next week to present our deep concerns about the Region using our CEG as a screening level above which there may be health concerns (and thus, for example, warrant an order to provide drinking water), and to give details on our new analytical method and sampling protocol. [We planned to provide the 3M advisory level of 6-7 ppb and draft Environ Monograph.]

She was very interested in these topics and voiced a sincere desire to accommodate our request, but next week simply is impossible given her schedule, and she feels she is an essential participant. She asked if we could cover these topics during our meeting with the WVDEP Oct 16, but when I learned Region 3 will cover by phone I said that likely would not give our presentation a fair hearing. She suggested we then meet right after the 16th, I said we are very concerned that the Region might issue an order using our CEG as a trigger for drinking water. She assured me the order is moving a bit slower than they had hoped and that they would not issue it until they had heard our concerns. This extra breathing room may be a good thing, but may be best if we do not have first results (if high) from the new technique for our first meeting.

Shall we try to meet with the Region later that week, e.g. Oct 17, 18, or 19? I am good those days, how about the remainder of our tox subteam (Gerry, Rob, Dave, Ann, Andrew, Izzy, Bob P?? Also good Oct 22 and 24.

--Bernie

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