Secretaries' Science Advisory Board

MEETING SUMMARY
Ground Floor Hearing Room of Archdale Building

March 19, 2018

10:00 AM – 12:30PM

The Department of Environmental Quality (DEQ) and the Department of Health and Human Services (DHHS) Secretaries' Science Advisory Board (SAB, or Board) met on Monday, March 19, 2018, in the Ground Floor Hearing Room of the Archdale Building in Raleigh. The SAB members in attendance were as follows: Dr. Jamie Bartram, Ph.D. (Chair), Dr. Tom Augspurger, Ph.D., Dr. Richard T. Di Giulio, Ph.D., Dr. David Dorman, DMV, Ph.D., DABVT, DABT, Dr. Elaina Kenyon, Ph.D., DABT, Dr. Thomas Starr, Ph.D., MD, MSPH, Dr. Michael Stoskopf, DVM, Ph.D., DACZM, Dr. John Vandenberg, Ph.D., Dr. Betsey Tilson, MD, MPH, Mr. Phillip Tarte, MPH, Dr. Jaqueline MacDonald Gibson, Ph.D., Dr. Gina Kimble, Ph.D., and Dr. Viney Aneja Ph.D. Dr. Detleff Knappe and Dr. Stopford were not in attendance. Also in attendance were DEQ Assistant Secretary Sheila Holman, DEQ and DHHS support staff, and media.

I. Call to Order (Chairman Jamie Bartram)

Chairman Bartram called the meeting to order.

II. Ethics Statement

Chairman Bartram read the ethics statement and reminded the members that if anyone had any potential conflict of interest to so indicate. No one identified conflicts.

III. Approval of January 29, 2018 SAB Meeting Minutes

The January 29, 2018 meeting minutes, with changes received were circulated to members prior to the meeting. They contain a clarification from Dr. Vandenburg that his comment was for EPA staff to support training of NC state staff in using the benchmark dose models, not that EPA would be doing the modeling for GenX, the January meeting minutes were approved unanimously.

To reduce significant overlap with posted audio recordings and use staff and members' resources efficiently, Chairman Bartram suggested that future meeting summaries be less detailed and capture critical issues discussed, decisions reached and decisions/actions that are/remain outstanding. The Board members concurred.

Chairman Bartram noted that members received a lot of background material including several letters and papers prior to the meeting including those by Shea, Dewitt, and Belcher.

IV. Update from Vegetable Study from Netherlands and Minnesota Study (DEQ)

Presentation by Michael Scott, Director of Division of Waste Management, DEQ

Director Scott stated that DWM staff has been working on the groundwater assessment related to the Chemours facility in Bladen County. A major component of that work has included

groundwater sampling of private drinking water wells by both Chemours and DEQ. DEQ has evaluated the current groundwater data and has looked for sources of the contamination while also evaluating other media that may need further investigation.

Director Scott provided an update on the vegetable study from the Netherlands. The study looks at the presence of GenX garden crops. DEQ received a copy of this study about a week and a half prior to the meeting; and since it was in Dutch, it was translated to English by department staff. The department is awaiting a formal English version. The study asked two key research questions: 1) What are the concentrations of GenX and PFOA in selected crops from vegetable gardens in the vicinity of the DuPont Chemours facility in the Netherlands?; and 2) Is the allowable daily intake, referred to as the TDI, via food from GenX and PFOA exceeded by consumption of vegetable crops in a typical consumption pattern.

The study was performed at the request of the Netherlands National Institute for Public Health and the Environment per request from the city of Dordrecht. Sampling occurred at the end of August 2017 and went out to a 4 km radius around the plant. Three samples for GenX and PFOA analysis were taken from Dordrecht, three samples from Papendrecht, and four samples from Sliedrecht. Vegetables sampled included primarily leafy type vegetables (endive and lettuce) and tuber type vegetables including beets, carrots, and potatoes, and seed-baring vegetables including bell peppers and tomatoes. Apples and pearswere sampled at one location. A total of 81 samples were collected. A second phase study on soil and water data in the Netherlands is planned.

GenX was quantified in five crops: endive, beets, celery, lettuce, and tomatoes. The highest average concentration found was 5.4 ng of GenX per gram of lettuce. PFOA was only able to be quantified in beets with the concentration being 2.5 ng per gram of beets. All high levels were found northeast of the plant in Dordrecht.

Based on staff's initial review of the unofficial translation, key conclusions include the following:

- The highest concentrations were from samples within 1 km of the plant.
- The above maximum values were used in the exposure for the TDI equation so the level is conservative in how it was calculated. It was also assumed that someone would use vegetables from their garden daily versus consuming vegetables from other sources.
- Main conclusion - There are considerations for other exposure related to drinking water and some further work needs to be looked at related to particulate exposure potentially via air.
- Key recommendation - Vegetables within 1 km radius of the plant are not to be consumed "too often", which staff took to means more than 3 times daily. The study did not recommend any limited consumption or use beyond that radius.
- Main conclusion 1- Exposure via food for PFOA and GenX did not exceed health based limits when looking at average daily intake for individuals.
- Main conclusion 2 - A recommendation was made that garden owners and those who use their gardens frequently within 1 km of the facility not consume too much of the vegetables from their own base gardens, due to the potential for additional exposure from air and water.

Another study was conducted by the Minnesota Department of Health (MDH) in areas where high levels of PFCs were found in drinking water. Sources of drinking water were ultimately utilized for irrigation for residential gardens. Samples were collected from approximately twenty homes including water, soil and produce sampling. PFBA was detected in 98% of the vegetable samples. The MDH conducted a health risk assessment following the 2010 study for five PFCs for which safe dose levels have been established, which included PFOA, PFOS, PFBA, PFBS, and PFHxS. The MDH risk assessment determined that no health risks of concern were found when considering combined risks from all exposure pathways including ingesting water, consumption of produce, and inhalation of household dust; but the study indicated that assessments of risk to short-chain PFAS in areas with contaminated water should include homegrown produce in addition to the other exposure pathways.

One conclusion that DWM is looking at closer as DEQ evaluates the presence of these compounds in the environment includes some statements related to shorter carbon chain compounds and their ability to translocate in the plant, how it may differ from some of the longer C8 chain compounds, and whether there is variation in their ability to bioaccumulate.

Director Scott noted that DEQ completed fish tissue sampling at a private lake just north of the Chemours plant earlier in the month and hopes to have results to share with the SAB when available.

Board Discussion

Considerations included whether the agency was looking at potential for deposition as a source of contamination, whether other food sources were being considered for/sampled for GenX, whether bioaccumulation potential was being modeled, whether risk from multiple compounds would be added suggesting that the Board may need to look at toxic equivalency type approach for classes of compounds. Director Scott noted DEQ has broadened its analytical look to 20-30 compounds, but DEQ's focus has been on the residential garden.

A question arose as to whether either of the studies speak to deposition. Director Scott noted that the Netherlands study mentioned deposition but the Minnesota study appears to be focused on a residential drinking water source used for irrigation. It was noted that a member had read in the media that downwind of the plant in Fayetteville rainwater sampling was occurring and the member asked if DEQ had examined or studied how rainwater had become contaminated.

Mike Abraczinskas, Director of the Division of Air Quality, DEQ, responded that DAQ has conducted some rainwater sampling at Chemours Fayetteville Works and is looking at all media. DAQ has also reviewed rainwater data that UNCW is collecting on its own. DAQ has collected 5-6 wet deposition rainwater samples offsite from Chemours since January and found GenX to be present. Control samples were also collected in Raleigh all of which were non-detect. Analysis found a general match between surface wind direction and presence of GenX in rainwater samples. A key question is how fast C3 dimer converts into GenX. There was also a question regarding whether there is any strategy to determine how contaminated water enters the river and whether that avenue is being looked at. Director Scott noted that strategy is being finalized. Whether there should be food/fish advisories would be a second part of the process and DEQ would make a decision with its other agency partners.

The work being done was applauded by members and it was noted that other potential exposure should also be looked as some members have heard that GenX had been found in honey as well and asked if insect bioaccumulation effect is being looked at. Director Scott noted that DEQ worked with DHHS to consider the amount of honey that would have to be consumed to be problematic and it was considerably more than one would ever consume daily.

The question was asked whether anyone was aware of any efforts to model bioaccumulation potential noting she would be very interested in that information and that it could be useful for the SAB as it looks at prioritization of chemicals or classes of chemicals moving forward in a phased approach. Dr. Tilson noted that there is work going on at the federal level and also with other states.

A caution and question regarding how all the data being collected might be used in terms of development of a health goal given that it is a multimedia issue was posed. It was suggested that the information could help inform the consideration of whether the default 20% value is an appropriate relative source contribution for health goal calculations or could point to the need for addressing another media. Chair Bartram noted the SAB is trying to move as fast as it can with a relatively thin set of evidence, hears the pleas of the public, and is trying to find the right balance of information to move forward appropriately.

Action Item
DWM will continue reviewing Netherlands study, provide the formal English version when available, and follow up on why the such a low value for TDI relative to the reference dose was chosen and how they set their reference level.

V. PPARα Concerns (DHHS)

Presentation by Mina Shehee, PhD, Head of the Occupational and Environmental Epidemiology Branch (OEEB), Department of Health and Human Services, Dr. Shehee provided information on rationale on Peroxisome Proliferator-Activated Receptor (PPARα) mechanism of action relevance to human health in follow-up to questions from the previous meeting. An article by Corton et al, argues that a number of agents, including PFAS, cause liver tumors in rodents via a mode of action that includes activation of PPARα and that mode of action isn't relevant to humans. In EPA's Lifetime Health Advisories and ATSDRs draft Tox Profile for PFAS, DHHS finds that there is evidence of interspecies difference in levels of PPARα expression and responsiveness and that there are also PPARα-independent mechanisms involved in PFOA and PFOS toxicity such as liver toxicity. In addition, the end point DHHS uses was a non-cancer endpoint. As a result, relevance of these endpoints to human health cannot be excluded.

The Board discussed the topic of PPAR**α.** It was suggested that a discussion of uncertainties regarding mode of action including what is known and what is not known be included in introductory material regarding any SAB recommendation and ultimately that the health endpoints be allowed to drive derivation of a recommendation rather than mode of action.

VI. Status Update on Benchmark Dose Modeling (DHHS)

Mina Shehee, PhD, Head of the Occupational and Environmental Epidemiology Branch (OEEB), Department of Health and Human Services, provided an update on EPA's health goal for GenX, and also presented progress on Benchmark Dose Modeling efforts by DHHS. Ms. Shehee reported that EPA is working on a GenX goal and has a goal of 5 months to establish a level, but that timing is uncertain. DHHS intends to continue working on GenX benchmark dose modeling.

Action Item
DHHS will provide the Board the name of the EPA lead contact for the GenX goal effort and identity of the other PFAS for which EPA health goal work is proceeding.

OEEB staff have received training on the benchmark dose modeling from EPA staff. Staff have reviewed the 7 GenX oral toxicity studies that are relevant to provisional health goal for drinking water and created data tables for each statistically significant endpoint for GenX. Dr. Shehee reviewed the organization of information in the tables. NC DHHS requested input from the SAB on: 1) what endpoints they deemed critical and/or most relevant to human health to use as input into the BMD software; and 2) guidance/justification on benchmark response levels for each endpoint identified as input to the BMD model. OEEB staff will use EPA's BMD software to model the selected endpoints at the recommended response levels and will provide outputs of the model (BMDLs) for SAB consideration and recommendation for use as a point of departure.

Considerable discussion occurred regarding appropriate study endpoints for use as inputs for the model including whether only cases that showed statistical significance were to be used, whether that is appropriate, as well as portraying model output across multiple studies using model features for ease of comparison.

In preparing data tables for each of the studies DHHS didn't do any statistical analysis of the studies, but rather used or relied on analysis by the study authors. Apparent data trends should also be considered. It was noted that it may be more difficult to decide what not to model rather than to run all the data sets. Dr. Shehee noted that this modeling would take time and sought clarification as to whether the Board wants DHHS to run all of the data sets for which tables were provided.

Concerns were raised that statistical significance may not be the appropriate determining factor regarding what studies/endpoints should be modeled and that use of statistical significance can inappropriately screen out relevant data. Expert judgement needs to be applied in determining what studies/endpoints to include in the modeling inputs and obvious data trends should also be considered.

Ultimately, Chairman Bartram noted that the Board advises and the state decides and requested volunteers from the Board with expertise in benchmark dose modeling to assist with guiding DHHS staff on the BMD modeling exercise.

Action Item
Dr. Vandenburg and Dr. Dorman will provide further guidance and advice to DHHS staff regarding BMD model inputs based on their experience via conference call.

The Chairman and Board members noted that DHHS had done a great job summarizing the study information and that was a big step forward for the process.

Chairman Bartram posed four lingering questions to DEQ:

1) What is the progress on actual stack data?
Director Abraczinskas said that stack testing to obtain the first emission measurements of GenX occurred in January. As far as he knows, this is the first instance of stack testing for GenX in the world. DAQ is reviewing the preliminary report and anticipates releasing the results in the next weeks.

2) The Board heard mention about modeling of deposition, soil transport, and vegetable uptake. Are there any plans to look for these substances of interest directly in vegetables in North Carolina?;
There has not been any modeling of soil yet. DEQ has requested and received data from Chemours on-site soil sampling only. No direct vegetable testing has occurred at this time, but would be a next step discussion with the Department of Agriculture. DEQ has not determined whether vegetable testing is needed yet.

3) When will the Board see local fish testing data?
Fish tissue data from a private lake was received the week before last and serves as just a starting point trying to answer questions related to bioaccumulation.

4) Has the possibility of establishing a local advisory as was done in the Netherlands been discussed with DHHS?
Fish tissue sampling from the private lake conducted the week before would not be appropriate data to use for a local advisory for the Cape Fear. Water body specific fish tissue testing would be needed to determine whether an advisory would be appropriate for Cape Fear river.

Discussion occurred regarding where air emissions data is measured, what form is measured and whether fugitive emissions might be missed. Director Abraczinskas stated that ongoing stack testing would characterize a portion of the stack emissions profile of GenX and focused on what were believed to be the highest emissions points. A stack test method had to be developed in conjunction with EPA and Chemours and a stack testing firm to be confident of capture. There is not a lot of agreement regarding how to measure GenX in ambient air, but there is confidence in how to measure it in water. DAQ has collected 5-6 wet deposition rainwater samples offsite from Chemours since January and found GenX to be present. Control samples were also collected in Raleigh all of which were non-detect. Analysis found a general match between surface wind direction and presence of GenX in rainwater samples. A key question is how fast C3 dimer converts into GenX.

Whether vegetable testing, if it were to be done, would be just in personal gardens or commercial farming and whether it would include only GenX or other PFASs was also discussed. A question was asked regarding whether a land use study related to agricultural production in the zone of

interest is being done. DEQ responded that its focus has been on the home garden. The agency is in discussion with Department of Agriculture on the agricultural topic.

Action Item

It was suggested that DEQ request a mapping by radius of what land use is from its Department of Agriculture partners. The Board requested that DEQ, DHHS and Department of Agriculture discuss and provide a more comprehensive, rounded view of what is going on related to food stuffs at the next meeting.

VII. Overview of Regulatory Standards (DEQ)

a. Presentation by Jessica Godreau, Chief of the Public Water Supply Section - Drinking Water

Jessica Godreau, Chief of the Public Water Supply Section, provided an overview of drinking water standards and development of regulations covering the North Carolina Drinking Water Act, what constitutes a public water system, the Federal Safe Drinking Water Act, the federal regulation development process and considerations, and considerations and constraints for development of state regulations.

b. Presentation by Chris Ventaloro, DEQ - Ground Water and Surface Water

Mr. Ventaloro provided an overview of how North Carolina ground water and surface water standards are developed and applied including what criteria the standards protect for, how the standards are calculated, the associated state, and for surface water federal, review processes. Surface water standards protect surface water for a variety of uses and include health related criteria for fish consumption and water supply. Groundwater standards protect groundwater as a resource for human consumption based on health-related criteria and do not consider the cost of treatment. The standards are set through a triennial review process.

VIII. Public Forum

Ms. Dana Sargent, Cape Fear River Watch, expressed concern regarding questions she heard from the Board members during the meeting regarding what could be done regulatorily noting that the description of the SAB's role includes working with DEQ as consultants in working out regulatory standards. She expressed frustration thinking about the timeline and questioned whether any discussions with DEQ are occurring between meetings to help formulate a regulatory standard. She questioned whether the Board will have to wait for all data from soil, fish, etc., to be discussed to make a recommendation. Given that knowledge and information is very thin regarding other exposure routes, she questions whether those factors will influence the outcome.

Chairman Bartram responded that although it may not be obvious to those listening to the Board's conversations, their technical discussions regarding mechanism of action and toxicity are intended to help point to a number for a regulatory determination. It was also noted that the Board exists to provide advice, not to set a regulatory standard itself which will require policy judgements and is not their role. Chairman Bartram also noted the Board doesn't necessarily have to wait but they

have to weigh which items to factor in as they wouldn't want to recommend something that could be harmful due to a gap in knowledge or information. He thanked Ms. Sargent for her comments.

Michael Waters, a resident of the Grays Creek area, noted that he lives 1 mile away from the plant. He volunteered to have crops from his garden tested. Fourteen chemicals have been found in his well at concentrations of 510 PFAS and 236 GenX. He is setting up a water wick and bringing in clean soil to plant two test gardens one of which will be in a greenhouse. He volunteered to provide some of his crops to the state or anyone who wants to test them. He has already spent $1600 on well testing. He also encouraged fish tissue testing in the area of Marshwood Lake. Mr. Waters noted that in one subdivision of nine homes six families have had members who have had cancer in the last ten years. He noted that other states such as New Jersey and Michigan have much lower (i.e., more stringent) standards for GenX than North Carolina and 140 is kind of high. He provided the caveat that most of the other states' standards he referenced are for PFOA and PFOS. Mr. Waters said that the Netherlands are way ahead of us and that he appreciates the work that is going on here.

Chairman Bartram thanked Mr. Waters for his comments and scientific approach to the issue.

IX. Next Meetings

Chairman Bartram noted that the next meetings of the Board are scheduled for April 30th, June 18th, and July 26th. An additional meeting is suggested to be held August 30th. Dr. Di Guilio noted an earlier date would be preferable to avoid university end of fiscal year issues.

A member encouraged the state to look at commercial farms and fish farms in its work in addition to home gardens.

Interest was expressed in SAB members touring the Chemours facility. Chairman Bartram noted that two interests had been expressed, one being touring the facility and the other being holding a meeting near the facility. He inquired as to whether visiting the facility would be possible. Assistant Secretary Holman stated the Department would need to contact the facility to see if they would be amenable to a tour.

Action Item
A follow up poll of Board members' interest in the tour will be conducted via email.

Chairman Bartram asked if members had any other comments and hearing none adjourned the meeting.