N.C. DHHS Staffing for GenX Response and Calculation of Provisional Health Goal

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N.C. DHHS Staffing for GenX Response

- Public health roles in response
  - Determine whether compounds detected through environmental sampling could pose a risk to human health
  - Provide health-based guidance on levels of exposure to such contaminants
  - Conduct risk assessments and risk communication
- Identify Department resources/staff performing these functions and provide relevant detail

Occupational and Environmental Epidemiology

Program Manager

Office Assistant

OCCUPATIONAL SURVEILLANCE

Public Health Epidemiologist

PRIVATE WELLS

Environmental Program Consultant

CLIMATE AND HEALTH PROGRAM

Environmental Program Consultant

Public Health Educator

CHEMICAL PREPAREDNESS AND RESPONSE

Environmental Program Consultant*

Public Health Epidemiologist

HEALTH ASSESSMENT, CONSULTATION AND EDUCATION PROGRAM

Environmental Program Consultant*

Environmental Program Consultant*

Public Health Educator*

MEDICAL EVALUATION AND RISK ASSESSMENT

Medical Consultant*

Public Health Epidemiologist*

Environmental Toxicologist*

Office Assistant

INDUSTRIAL HYGIENE CONSULTATION

Industrial Hygiene Consultant

Industrial Hygiene Consultant

Processing Assistant

OCCUPATIONAL NURSE CONSULTATION

Nurse Consultant

KEY

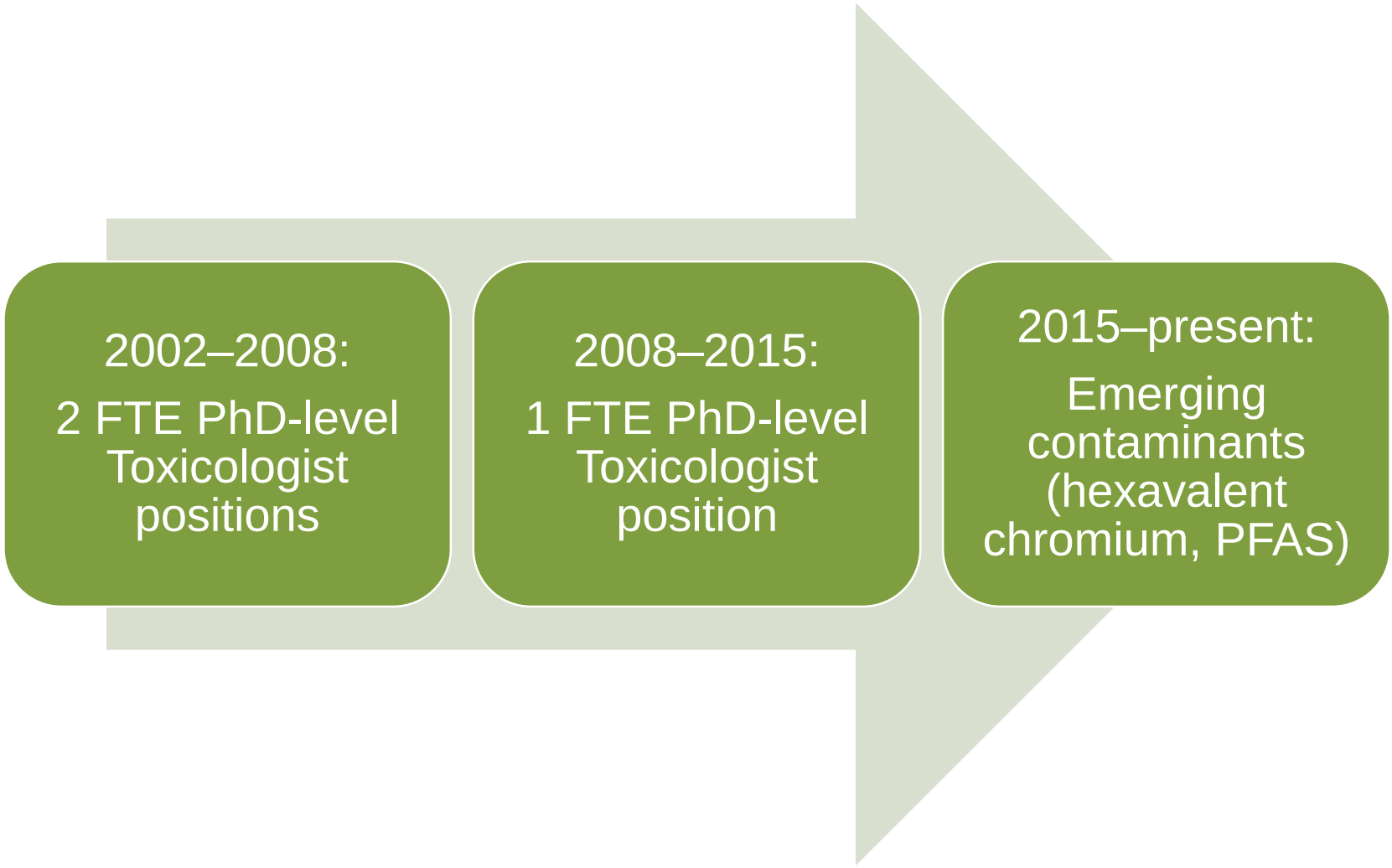
Federal: 9 FTE | State: 10 FTE

* Involved in GenX response

Staff Resources for GenX Response

- Environmental Toxicologist
- Environmental Program Consultants
- Public Health Educator
- Medical Consultant
- Public Health Epidemiologist

Timeline of Environmental Epidemiology



N.C. DHHS Provisional Health Goal

- Describe research and studies that contributed to the establishment of the 140 parts per trillion health goal for GenX
- Provide relevant detail regarding sources of data (studies, etc.) and processes used in developing the health goal

What is a Health Goal?

- Level of contamination below which no adverse health effects would be expected over a lifetime of exposure
- Calculated based on the most vulnerable population
- Non-regulatory, non-enforceable
- Change as new information becomes available

Health Goal: Requirements

- Must have sufficient health-related information
  - Animal studies
  - Epidemiologic studies (human health)
  - Other laboratory studies
- Some health-related information not in public domain
- Health-related information often lacking for emerging compounds

Health Goal: Calculations

- Health Goal = (*Reference Dose* x *Relative Source Contribution* x Body Weight) ÷ Intake Rate
- Reference dose = *No Adverse Effect Level* ÷ *Uncertainty Factors*
- Terms to define:
  - No Adverse Effect Level (NOAEL)
  - Reference dose (RfD)
  - Uncertainty Factors (UF)
  - Relative Source Contribution (RSC)

https://www.epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments

Definitions: No Adverse Effect Level (NOAEL)

- Used as Point of Departure for calculations
- Experimentally determined dose at which there is no statistically or biologically significant indication of the toxic effect of concern
- Usually based on laboratory animal studies

https://www.epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments

Definition: Uncertainty Factors (UF s)

- Factors used in calculations to represent specific areas of uncertainty in the available data
- Standard UFs include
  - **Intraspecies UF**: Accounts for variation in sensitivity among the members of the human population
  - **Interspecies UF**: Accounts for uncertainty involved in extrapolating from animal data to humans
  - **Subchronic to chronic UF**: Accounts for uncertainty involved in extrapolating from less-than-chronic NOAELs to chronic NOAELs

https://www.epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments

EPA Guidance for Use of Uncertainty Factors

- Use a 10-fold factor when extrapolating from valid experimental results in studies using prolonged exposure to average healthy humans
- Use an additional 10-fold factor when extrapolating from valid results of long-term studies on experimental animals
- Use an additional 10-fold factor when extrapolating from less than chronic results on experimental animals when there are no useful long-term human data

https://www.epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments

Definition: Reference Dose (RfD)

- Daily dose below which health effects are not expected in human populations (mg/kg/day)
- Derived from the NOAEL by consistent application of generally order-of-magnitude uncertainty factors that reflect various types of data sets used to estimate RfDs
- RfD = NOAEL ÷ UF

https://www.epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments

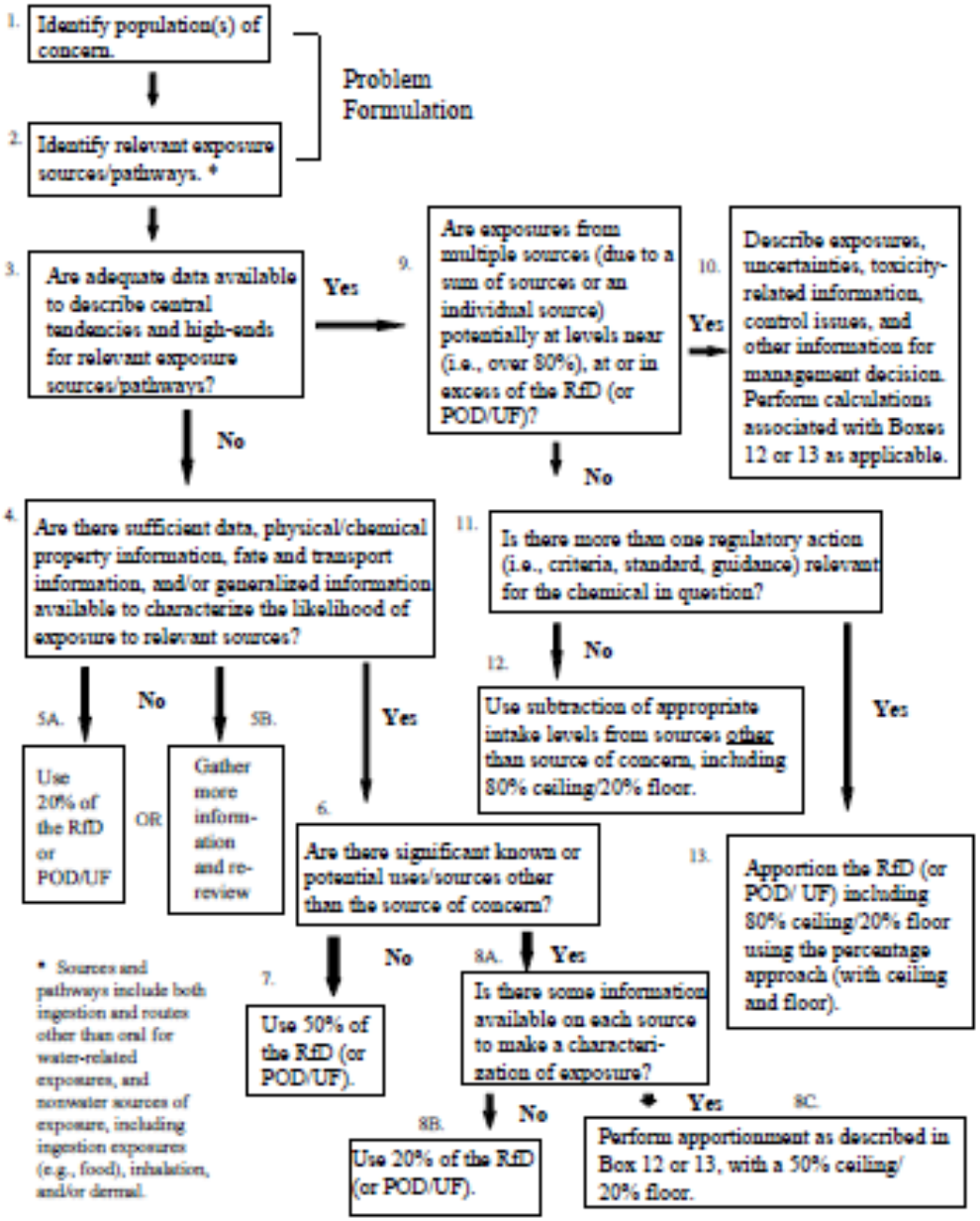
Definition: Relative Source Contribution (RSC)

- Percentage of reference dose exposure attributed drinking water
- Accounts for possibility of non-water sources of exposure, such as
  - Foods
  - Inhalation
  - Skin absorption
- Guidelines available from EPA for compounds with limited data
- 20% RSC used for GenX health goal calculations

https://nepis.epa.gov/Exe/ZyPDF.cgi/20003D2R.PDF?Dockey=20003D2R.PDF

Figure 4-1

Exposure Decision Tree for Defining Proposed RfD (or POD/UF) Apportionment



Point of Departure for GenX Health Goal

- NOAEL = 0.1 mg/kg/day
- Based on 28-day oral ingestion mouse study conducted by Chemours (2008)
  - 0 mg/kg/day……(20 male, 20 female)
  - 0.1 mg/kg/day…(10 male, 10 female)
  - 3 mg/kg/day…….(10 male, 10 female)
  - 30 mg/kg/day…..(20 male, 20 female)
- NOAEL based on liver effects in male mice

https://echa.europa.eu/registration-dossier/-/registered-dossier/2679/7/6/2/?documentUUID=7fde65ec-5187-42ef-8e05-58436035a555

Calculation of GenX Reference Dose

- Reference dose (RfD) = NOAEL ÷ UF
  - NOAEL = 0.1 mg/kg/day
  - UF = 1,000
    - 10 intraspecies
    - 10 interspecies
    - 10 subchronic to chronic
- RfD = 0.1 mg/kg/day ÷ 1,000
- RfD = 0.0001 mg/kg/day

https://ncdenr.s3.amazonaws.com/s3fs-public/GenX/NC%20DHHS%20Risk%20Assessment%20FAQ%20Final%20Clean%20071417%20PM.pdf

Calculation of GenX Health Goal

- Health Goal = (Reference Dose (mg/kg/day) x RSC x body weight (kg)) ÷ intake rate (L/day)
- Used body weight and intake rate values for bottle fed infants to calculate the most health protective goal to protect the most vulnerable
- Health Goal = (0.0001 mg/kg/day x 0.20 x 7.8 kg*) ÷ 1.113 L/day**
- Health Goal = 0.00014 mg/L = 140 ppt

* EPA EFH Table 8-1: Weighted average of mean body weight from 0-12 months [EPA 2011, ATSDR 2016a]

**EPA EFH Table 3-1: Weighted average of 95th percentile for consumers from 0-12 months [EPA 2011, ATSDR 2016b]

Provisional Health Goal: Considerations

- Applies only to GenX, not related compounds
  - Sufficient information not available to calculate health goals for other emerging per- and polyfluorinated compounds
  - Sufficient information not available to assess additive risk of all per- and polyfluorinated compounds in combination
- Represents level of chronic exposure which is not likely to result in adverse effects to humans
- Subject to change based on new information

Questions?