Dec 6, 2023

Ongoing PFAS Toxicology Studies – Status Update

Frannie Nilsen, PhD
DEQ Environmental Toxicologist

Topics Covered

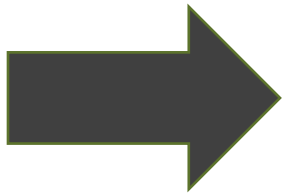
1. Consent Order Studies

2. Ongoing Federal PFAS Toxicology Studies

3. Ongoing Academic PFAS Toxicology Studies

PFAS in North Carolina

Consent Order Paragraph 14 Study PFAS



- PFMOAA
- PMPA
- PFO2HxA
- PEPA
- Nafion BP2

Chemours Consent Order: Toxicity Study Details

"The following studies, which shall be conducted following applicable USEPA, OECD protocols as defined in the USEPA TSCA, OPPT or other appropriate programs as determined by DEQ."

Rodent Toxicity Studies:

- 28-day oral immunotoxicity study in rats
- 28-day oral immunotoxicity study in mice
- 90-day repeated dose oral toxicity study in rats
- 90-day repeated dose oral toxicity study in mice

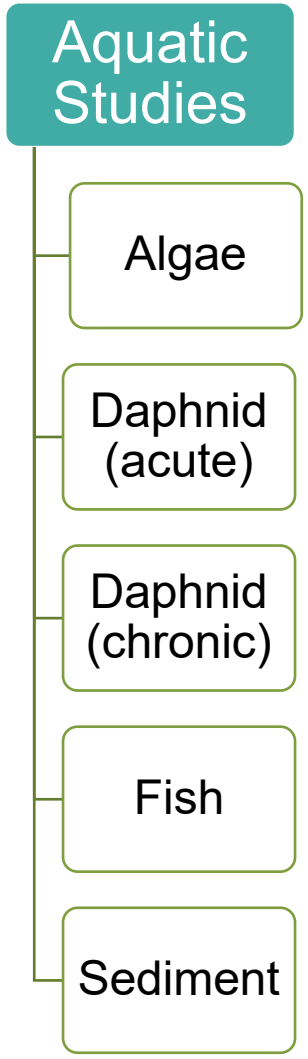
***Rodent Studies**: mouse and rat; classic tox and immunotox*

Ecological Toxicity Studies:

- Algal acute (72-hour growth) toxicity study
- Daphnid acute toxicity study
- Daphnid chronic (reproduction) toxicity study
- Fish acute toxicity study
- Sediment 10-day freshwater invertebrates toxicity test

***Aquatic Tox Studies**: algae, zooplankton, fish, and sediment worms*

Current Status of Consent Order Aquatic Toxicity Studies



Approval Steps:

- Protocols Approved – April & Dec 2022
- Range Finding Tests and Dose Approval – Jan – July 2023
- Definitive Tests Conducted – April – Nov 2023
- Final Report to DEQ – Algae expected Dec 2023;
  - all others in Early 2024

Current Status of Consent Order Aquatic Toxicity Studies

Aquatic Studies

- Algae
- Daphnid (acute)
- Daphnid (chronic)
- Fish
- Sediment

Approval Step	Algae	Daphia (acute)	Daphnia (chronic)	Fish	Sediment
Final Protocol Approval	April 2022	Dec 2022	Dec 2022	April 2022	Dec 2022
Range Finding Reports	Jan/Feb 2023	March-May 2023	May 2023	April/May 2023	*Expected Early 2024*
Analytical Method for Dose Validation	Feb 2023	May 2023	May 2023	May 2023	
Dose Approval for Definitive Tests	March 2023	June 2023	June 2023	Aug 2023	
Definitive Tests Conducted	May/July 2023	Sept 2023	Sept/Oct 2023	Aug-Oct 2023	
Final Reports to DEQ	*Expected Dec 2023*	*Data analysis and reporting underway at Eurofins*			

Current Status of Consent Order Rodent Toxicity Studies

Rodent Studies

- *Mouse 28-day Immune Tox*
- *Rat 28-day Immune Tox*
- *Mouse 90-day Classic Tox*
- *Rat 90-day Classic Tox*

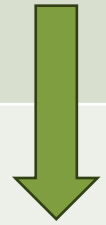
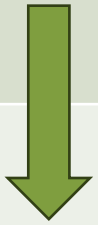
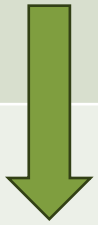
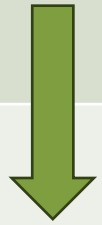
Approval Steps:

- Range Finding Tests and Analytical Method Validation
- Definitive Dose Approval
- Final Protocol Approved
- Definitive Tests Conducted
- Final Report to DEQ

Current Status of Consent Order Rodent Toxicity Studies

Rodent Studies

- *Mouse 28-day Immune Tox*
- *Rat 28-day Immune Tox*
- *Mouse 90-day Classic Tox*
- *Rat 90-day Classic Tox*

Step	Nafion BP2	PFMOAA	PMPA	PEPA	PFHO2xA
Analytical Method for Dose Validation	DEQ received July 2023; Approved HPLC-CAD Method				
Range Finding Reports	DEQ received July 28, 2023	DEQ received Oct 6, 2023			
Dose Approval for Definitive Tests	Meeting/Approval October 27, 2023				
Final Protocol Approval	*Next Step*				
Definitive Tests Conducted	*28-day tests first; 90-day tests will be informed by the 28-day dose-response*				
Final Reports to DEQ					

Ongoing Federal PFAS Studies

1. EPA ORD – Dr. Justin Conley
    1. GenX, Nbp2, PFOS in a rat dose additive maternal/offspring effects mixture study
        - Status: Published Sept 2023: https://doi.org/10.1016/j.scitotenv.2023.164609
    2. Developmental toxicity study of PFMOAA in rats, dose response experiment with exposure dosing during pregnancy and early lactation.
        - Status: Accepted for publication with minor revisions
    3. Companion studies from 5-day dosing of PFO4DA and PFO5DoA
        - Status: In prep for publication
    4. Toxicity mixture study with GenX, PFMOAA, PFOA, Nafion BP2, PFHxS, and PFOS
        - Status: Data analysis underway
2. NTP – Dr. Cynthia Rider
    1. PFOS, PFOA, PFBS, PFDA, PFHxA, PFHxS, PFNA mixture exposure in rats, for comparison to individual compound studies
        - Status: Data analysis underway
    2. Same PFAS list in different proportions, to match exposed population in NC
        - Status: Experiment design ongoing

NORTH CAROLINA Department of Environmental Quality

Ongoing Academic PFAS Studies

1. ECU – Dr. Tracey Woodlief
    1. Immune Tox studies of 6:2 FTS and PFPeA individually in mice
        - Status: In prep for publication; submission expected early 2024
    2. Immune Tox with PFO3OA and PEPA.
        - Status: to begin 2024
    3. Immune tox with PFOA/PFOS: PFPrA, MTP, Nafion Byproduct1, NVHOS individually and in mixtures
        - Status: submitted to the NC Collaboratory for funding (2024-2025)

2. OSU – Dr. Jamie DeWitt
    1. Immune Tox studies of PFMOAA and Nafion Byproduct2 individually in mice
        - Status: making final modifications before journal submission
    2. Immune Tox study of PFO5DA in mice
        - Status: Experimentation and Analysis ongoing

3. Duke – Dr. Nishad Jayasundara
    1. Zebrafish studies with the 5 CO PFAS
        - Status: Experimental design underway

Thank you

Frannie Nilsen, PhD
Environmental Toxicologist, Office of the Secretary
North Carolina Department of Environmental Quality
(919) 707-8217 | (919) 368-0205
Frannie.Nilsen@ncdenr.gov