EPA BIOSOLIDS PFOA & PFOS PROBLEM FORMULATION MEETING SUMMARY

November 10 & 12, 2020

Meeting Overview

- EPA held a meeting to gather stakeholder input on the PFOA and PFOS problem formulation for biosolids risk assessment. Day 1 of the meeting on November 10, 2020 brought together 72 participants from states and tribes. Day 2 of the meeting on November 12, 2020 brought together 170 participants from other biosolids stakeholder groups. The same content was covered on Days 1 and 2; meeting slides are attached to this summary. The meeting was led by Elyssa Arnold, EPA's Biosolids Risk Assessment Lead.
- Assessing the risk of chemicals found in biosolids is the Biosolids Program's top priority. EPA has heard the concerns about biosolids contaminated with PFAS, and is aware of the resulting uncertainty for states, treatment plants, land applicators, and other stakeholders. The PFOA and PFOS biosolids risk assessment is an important step to address that uncertainty and to provide an informed path forward.
- The PFOA and PFOS problem formulation for biosolids risk assessment is part of the EPA PFAS Action Plan.
- The problem formulation is the first step of risk assessment. It articulates the purpose for the assessment, defines the problem, determines the conceptual models, and describes the analysis plan. Problem formulation also includes engagement with states and tribes, risk managers, scientists, and members of the biosolids community to discuss foreseeable science and implementation issues.
- The purpose of the risk assessment is to determine potential risks from PFOA and PFOS in biosolids to public health and the environment in order to inform risk management options. This is in line with EPA's obligations under the Clean Water Act Section 405(d).

Defining the Problem

- PFOS and PFOA are part of a larger group of chemicals called per- and polyfluoroalkyl substances (PFAS).
- PFAS are highly fluorinated aliphatic molecules that have been released to the environment through industrial manufacturing and through use and disposal of PFAS-containing products.
- While many PFASs have been found in biosolids, PFOS and PFOA are among the most abundant and have the largest data sets to support risk assessment.
- PFOS and PFOA do not readily degrade via aerobic or anaerobic processes. The only dissipation mechanisms in water are dispersion, advection, and sorption to particulate matter such as biosolids in the wastewater stream.
- While PFOS and PFOA have largely been phased out of production in the United States, their resistance to environmental degradation causes a lingering concern for exposure. They can also be formed from precursors in the environment.

- PFOS and PFOA are both highly persistent in the environment and highly mobile. Both chemicals have a tendency to bioaccumulate in humans, terrestrial organisms, and aquatic organisms.
- PFOS and PFOA have been measured in biosolids in multiple published studies.

Questions for Meeting Participants

1. What sources of PFAS are you concerned about?
2. Is your state, tribe, or stakeholder group monitoring PFAS in biosolids, soils, surface or ground water?
3. Are you collecting other information that you think would be useful to EPA?
4. What challenges are you experiencing assessing the fate and transport of PFAS?
5. Is there anything else you would like us to consider as we define the problem of PFOA and PFOS in biosolids?

Key Input

- PFAS sources of concern include paper mills and residuals, industrial cleaning products, floor wax (*e.g.*, in schools), metal coating facilities, consumer products (*e.g.*, textiles), car washes, and aqueous film forming foam. Some sources of concern cannot be discussed due to ongoing litigation at the state level.
- Multiple states provided their PFOA and PFOS monitoring data to EPA.
- Analysis of concentration data needs to account for the laboratory methods used as well as changes in concentrations over time.
- Challenges in assessing fate and transport of PFAS include:
    - developing a measure of plant uptake, and
    - understanding transformation of PFAS compounds and precursors through the wastewater treatment process (oxidation, anaerobic concentration, composting, *etc.*).
- Biosolids and pretreatment programs are closely linked and should be considered together.
- The availability and cost of laboratory methods is an obstacle for states.

Conceptual Models

- Conceptual models were presented for land application, surface disposal, and incineration, which are the biosolids use and disposal pathways defined under 40 CFR Part 503.1. Human health receptors were addressed for all three pathways and ecological receptors were addressed for land application and incineration (surface disposal is excluded because the exposure pathways for surface disposal are not relevant for ecological risk assessment). The conceptual models can be found in the slides at the end of this meeting summary document.
- The conceptual models define the sources of exposure, routes of exposure, and receptors.
- Conceptual models are not intended to represent every possible route of exposure, but rather the primary ones that we are planning to model based on both
    1. the expected major pathways and
    2. the reality of the available data and modeling capabilities.
- The conceptual models represent the exposure pathways for all chemicals in biosolids and are not specific to PFOA and PFOS. The goal for the PFOA and PFOS risk assessment is to be consistent with the approach for all of EPA's biosolids chemical risk assessments going forward.

Questions for Meeting Participants

1. Do the conceptual models capture the range of routes of exposure of concern in your state, tribe, or stakeholder group? If not, what is missing?
2. Do the conceptual models capture the range of receptors of concern in your state, tribe, or stakeholder group? If not, what is missing?
3. Do the conceptual models capture the range of potential health effects of concern in your state, tribe, or stakeholder group? If not, what is missing?

Key Input

- Missing exposure pathways include:
  - home garden use for biosolids compost,
  - occupational exposure for professional land applicators,
  - occupational exposure for POTW workers,
  - groundwater used as drinking water for animals,
  - groundwater used as irrigation water,
  - human consumption of cow liver, and
  - other animal uses and consumption such as medicine, gelatin, and pet food.
- The incineration conceptual model is for SSIs and the source term does not currently include pyrolysis or gasification units.
- EPA will need more data in order to define PFAS destruction in SSIs.
- The conceptual model for incineration needs to better define the appropriate human receptors. The adult farmer and farm child may be less impacted than an urban population near an incinerator, and there may be disproportionate impacts to disadvantaged communities.
- Since PFAS are ubiquitous in the environment, the conceptual models should account for background levels of PFAS in soil, surface water, and ground water. PFAS may be present on land application sites due to pesticide applications.
- Similarly, human receptors have background PFAS exposure from drinking water and consumer products.
- The conceptual models do not include release mechanisms that are not regulated by the Clean Water Act, *e.g.*, disposal of ash or scrubber water from an incinerator (covered under the Resource Conservation and Recovery Act).

Analysis Plan

- Toxicity endpoints and bioaccumulation factors for the risk assessment for human health, aquatic life, and aquatic-dependent wildlife will be consistent with other efforts in the EPA Office of Water and across the Agency. Human health effects and bioaccumulation data support both ambient water criteria for human health and Safe Drinking Water Act regulatory determinations. Aquatic life and aquatic-dependent wildlife effects and bioaccumulation data support ambient water criteria for aquatic life and aquatic-dependent wildlife.
- Toxicity endpoints for non-aquatic dependent birds, mammals, terrestrial invertebrates, and terrestrial plants are currently being evaluated by the Biosolids Program.
- The modeling approach for biosolids risk chemical assessment is currently under development for presentation to the Science Advisory Board (SAB) in 2021. The approach includes a (1) chemical prioritization method, (2) a Biosolids Screening Tool for deterministic, screening-level assessment and (3) a probabilistic risk assessment framework for chemicals that fail at the screening level. PFOA and PFOS have already been prioritized for risk assessment, however the

prioritization method will be applied to all chemicals measured in biosolids including many other PFAS.
- Modeling for biosolids will be based on publicly available, previously peer-reviewed models for leaching, runoff, erosion, air dispersal, and plant uptake to the greatest extent possible.
- The approach for PFAS will be consistent, to the extent appropriate, with all other chemical risk assessment for biosolids.
- EPA will complete the PFOA and PFOS risk assessment after the modeling approach is reviewed by the Science Advisory Board. The risk assessment will also go through review and public comment.

Questions for Meeting Participants

1. Are you aware of reliable fate, transport, or toxicity data for various routes of exposure, receptors, or health effects that EPA should know about? If yes, please share.
2. Have you used any modeling approaches for PFAS that you would like to share with EPA?
3. Is there anything else you would like to share regarding modeling of PFOA and PFOS in biosolids?

Key Input

- NHDES and USGS are conducting a PFAS soil leaching study to calculate soil partition coefficients.
- A fate and transport model evaluation for PFAS in biosolids prepared by Arcadis and NCASI was completed in June 2020: https://www.ncasi.org/wp-content/uploads/2020/03/Arcadis-PFAS-Residuals-Modeling-v1-1.pdf
- Minnesota is especially concerned about the body burden of PFAS passed to infants. The state has a model they use for drinking water values and for water quality criteria protective of fish consumption. See: https://www.nature.com/articles/s41370%20018%200110%205
- Minnesota is trying to initiate a land-applied biosolids study that would test soil, pore water, surface water, ground water, and crop uptake. The study would begin during the next growing season.
- Vermont DEC, Stone Environmental, and NEBRA partnered to create a model for chemical leaching to ground water from land applied biosolids.
- Maine is conducting a small ground water leaching study that may be useful to EPA.

Risk Management and Implementation Considerations

- Risk assessment is the first step of a larger process and is done to identify risks that exceed the level of concern for human health and ecological receptors. The risk assessment will go through review and public comment.
- If EPA determines that PFOA or PFOS in biosolids may adversely affect public health or the environment, risk managers will consider options for numerical limitations and best management practices for these compounds. Any subsequent proposed regulation would go through a standard rulemaking process including intra-Agency and Office of Management and Budget review.

Questions for Meeting Participants

1. What considerations or concerns should EPA be aware of during risk management and implementation?

2. Do you have any other topics related to risk management or implementation that you would like to raise?

Key Input

- The approach to biosolids risk assessment and regulation for PFAS should have a high-level strategy that includes pretreatment and manufacturing. Source control rather than continuous removal of chemicals from biosolids is key. Wastewater treatment plant infrastructure improvements require large economic investments.
- Stakeholders need EPA to look at the big picture in order to protect the quality of biosolids for beneficial use. A moratorium on land application is not sustainable for the industry.
- All three use and disposal practices for biosolids (land application for beneficial use, surface disposal, and incineration) are critical for successful biosolids management. A fourth option, such as pyrolysis, would improve the stability of the industry but requires a large capital cost.
- PFAS contamination may create problems for incineration and landfilling of biosolids as well as land application.
- Environmental justice implications should be considered for incineration and for land application. The synergistic impacts of other constituents on vulnerable communities further compounds the issue.
- Any regulatory limits for PFAS need to be considered within the context of background PFAS levels in the environment and exposure to PFAS from sources other than biosolids.

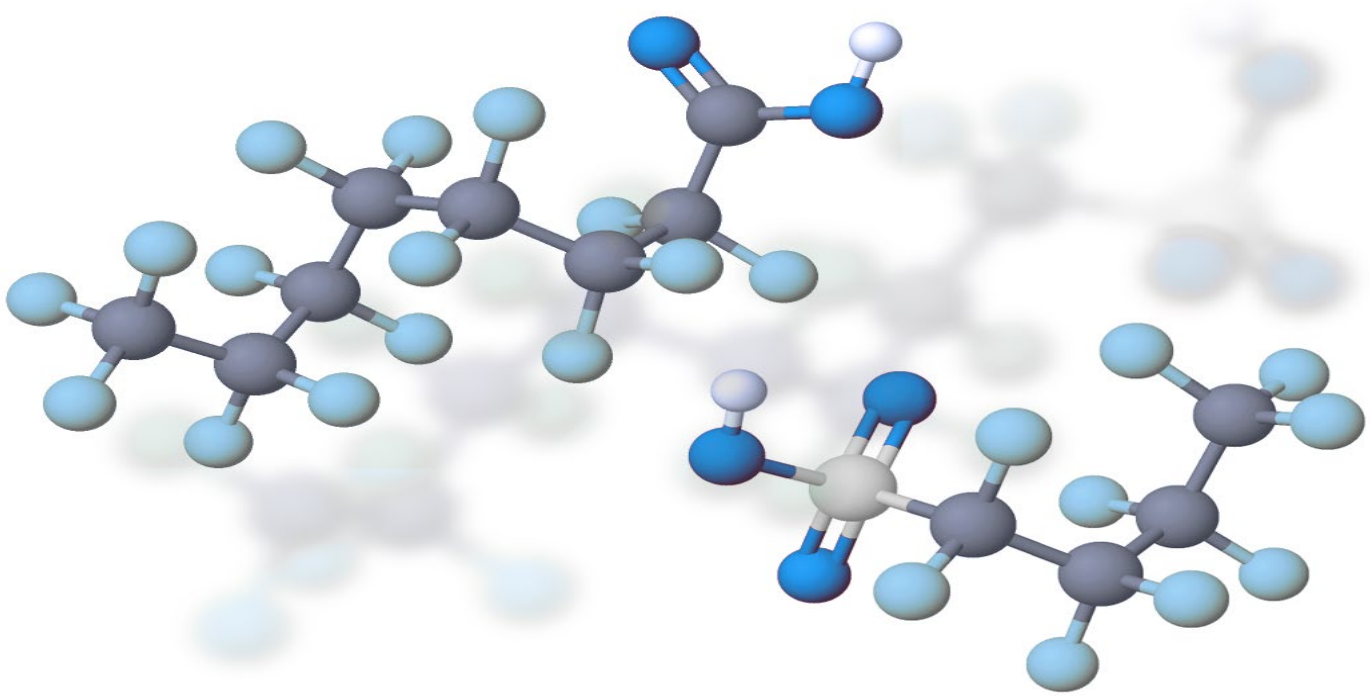
Next Steps

- Problem Formulation meetings completed December 2020; draft document expected Spring 2021.
- Science Advisory Board review of modeling approach expected to begin in 2021.
- Estimated completion of the risk assessment in 2022 for internal review, followed by public comment.
- If EPA determines that PFOA or PFOS in biosolids may adversely affect public health or the environment, risk managers will consider options for numerical limitations and best management practices for these compounds.
- If regulatory limits are advised, they will go through a standard regulatory process including peer review, inter-Agency and OMB review as well as public comment.

Attached: Meeting Slides

Biosolids PFOA & PFOS Problem Formulation Discussion with Stakeholders

November 10 & 12, 2020



Outline

- Introduction and Purpose
- Part 1: Defining the Problem
- Part 2: Conceptual Models
- Part 3: Analysis Plan
- Risk Management and Implementation Considerations

INTRODUCTION AND PURPOSE

Biosolids Risk Assessment in the PFAS Action Plan

- Activity: Scoping biosolids risk assessment for PFOA/PFOS
- Purpose: EPA is in the early scoping stages of risk assessment for PFOA and PFOS in biosolids to better understand the implications of PFOA and PFOS in biosolids to determine if there are any potential risks.
- Timeframe: 2020

https://www.epa.gov/pfas/epas-pfas-action-plan

Problem Formulation

Problem Formulation is the part of the risk assessment that:

- Articulates the purpose for the assessment
- Defines the problem
    - Chemical sources and occurrence
    - Fate and transport in the environment
    - Toxicity endpoints
- Determines the conceptual models (sources and routes of exposure) for assessing adverse effects to human health and ecological receptors (*e.g.*, birds, fish)
- Describes the analysis plan, documenting the approach for acquiring reliable data and the models and tools to be used in the analysis
- **Includes engagement with states and tribes, risk managers, scientists, and members of the biosolids community to discuss foreseeable science and implementation issues.**

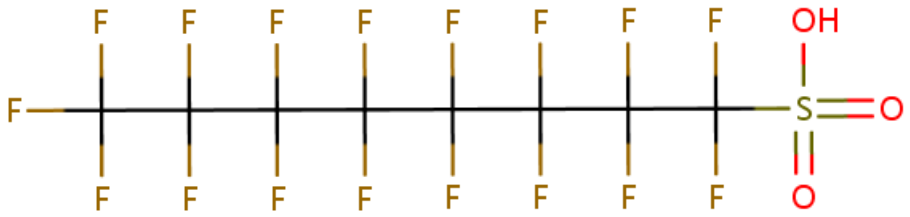
Purpose of the Risk Assessment

Determine potential risks from PFOA and PFOS in biosolids to public health and the environment in order to inform risk management options.

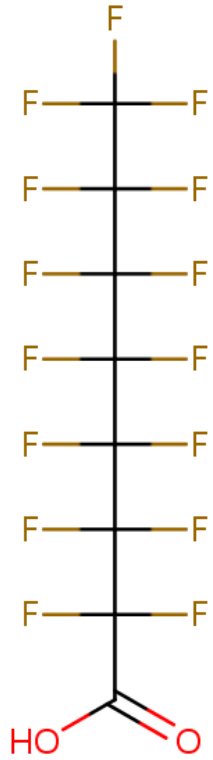
Clean Water Act, Section 405(d): EPA *"shall identify those toxic pollutants which, on the basis of available information on their toxicity, persistence, concentration, mobility, or potential for exposure, may be present in sewage sludge in concentrations which may adversely affect public health or the environment, and propose regulations specifying acceptable management practices for sewage sludge containing each such toxic pollutant and establishing numerical limitations for each such pollutant for each use identified under paragraph (1)(A)."*

DEFINING THE PROBLEM

PFOS and PFOA



Perfluorooctanesulfonic Acid (PFOS)
$C_8HF_{17}O_3S$
CASRN: 1763-23-1



Perfluorooctanoic Acid (PFOA)
$C_8HF_{15}O_2$
CASRN: 335-67-1

PFOS and PFOA Sources and Environmental Fate

- PFOS and PFOA are part of a larger group of chemicals called per- and polyfluoroalkyl substances (PFAS).
- PFAS are highly fluorinated aliphatic molecules that have been released to the environment through industrial manufacturing and through use and disposal of PFAS-containing products.
- While many PFASs have been found in biosolids, PFOS and PFOA are among the most abundant and have the largest data sets to support risk assessment.
- PFOS and PFOA do not readily degrade via aerobic or anaerobic processes.
- While PFOS and PFOA have largely been phased out of production in the United States, their resistance to environmental degradation causes a lingering concern for exposure. They can also be formed from precursors in the environment.

Concentrations of PFOA and PFOS in Biosolids

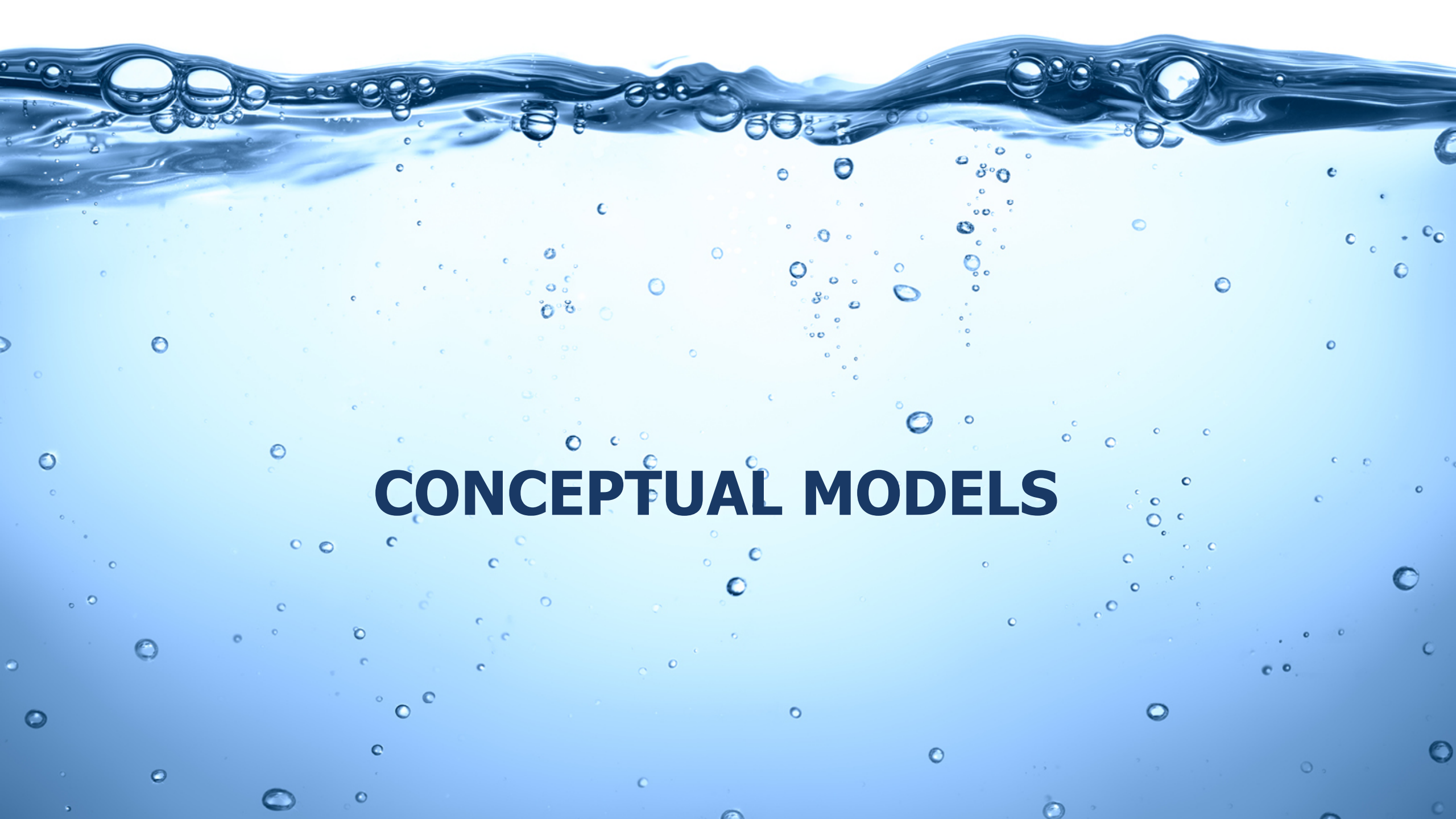
Year Sampled	PFOA (ng/g dry wt)	PFOS (ng/g dry wt)	Reference
2001	12 - 70	308 - 618	Venkatesan, 2013
2004-2007	8 - 68	80 - 219	Sepulvado, 2011
2005	16 - 219	8.2 - 110	Loganathan 2007
2005	18 - 241	<10 - 65	Sinclair, 2006
2006	--	81 - 160	Schultz, 2006
2006-2007	18 - 69	31 - 702	Yu, 2009
2007	20 -128	32 - 418	Yoo, 2009
2011	1 - 14	4 - 84	Navarro, 2016
2014	10 - 60	30 - 102	Mills, Dasu (in prep)
2018	1-11	2 – 1,100	EGLE, 2020

Defining the Problem

- Chemical sources and occurrence
- Fate and transport in the environment
- Toxicity endpoints

Questions

1. *What sources of PFAS are you concerned about?*
2. *Is your state, tribe, or stakeholder group monitoring PFAS in biosolids, soils, surface or ground water?*
3. *Are you collecting other information that you think would be useful to EPA?*
4. *What challenges are you experiencing assessing the fate and transport of PFAS?*
5. *Is there anything else you would like us to consider as we define the problem of PFOA and PFOS in biosolids?*



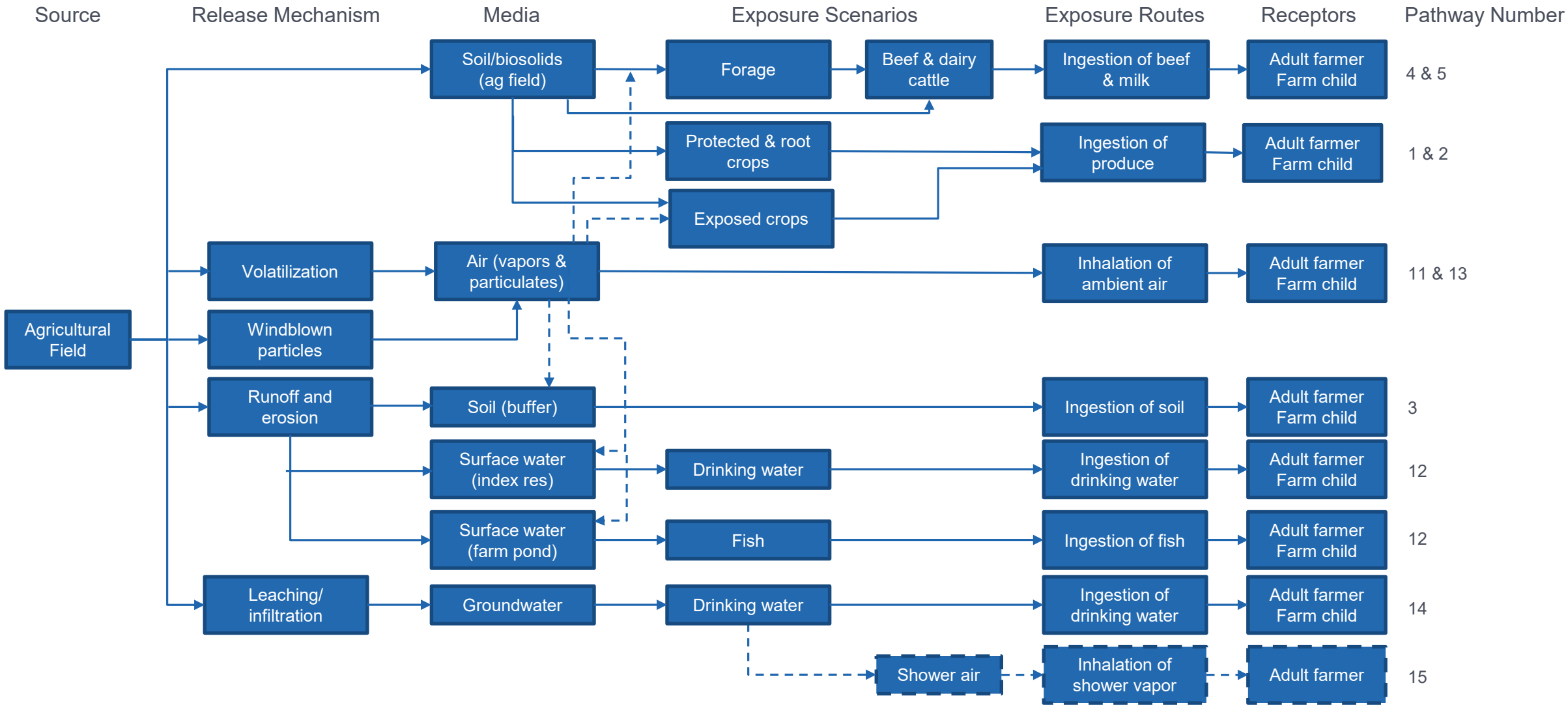
CONCEPTUAL MODELS

Biosolids Use and Disposal Pathways

1. Land Application
2. Surface Disposal
3. Incineration

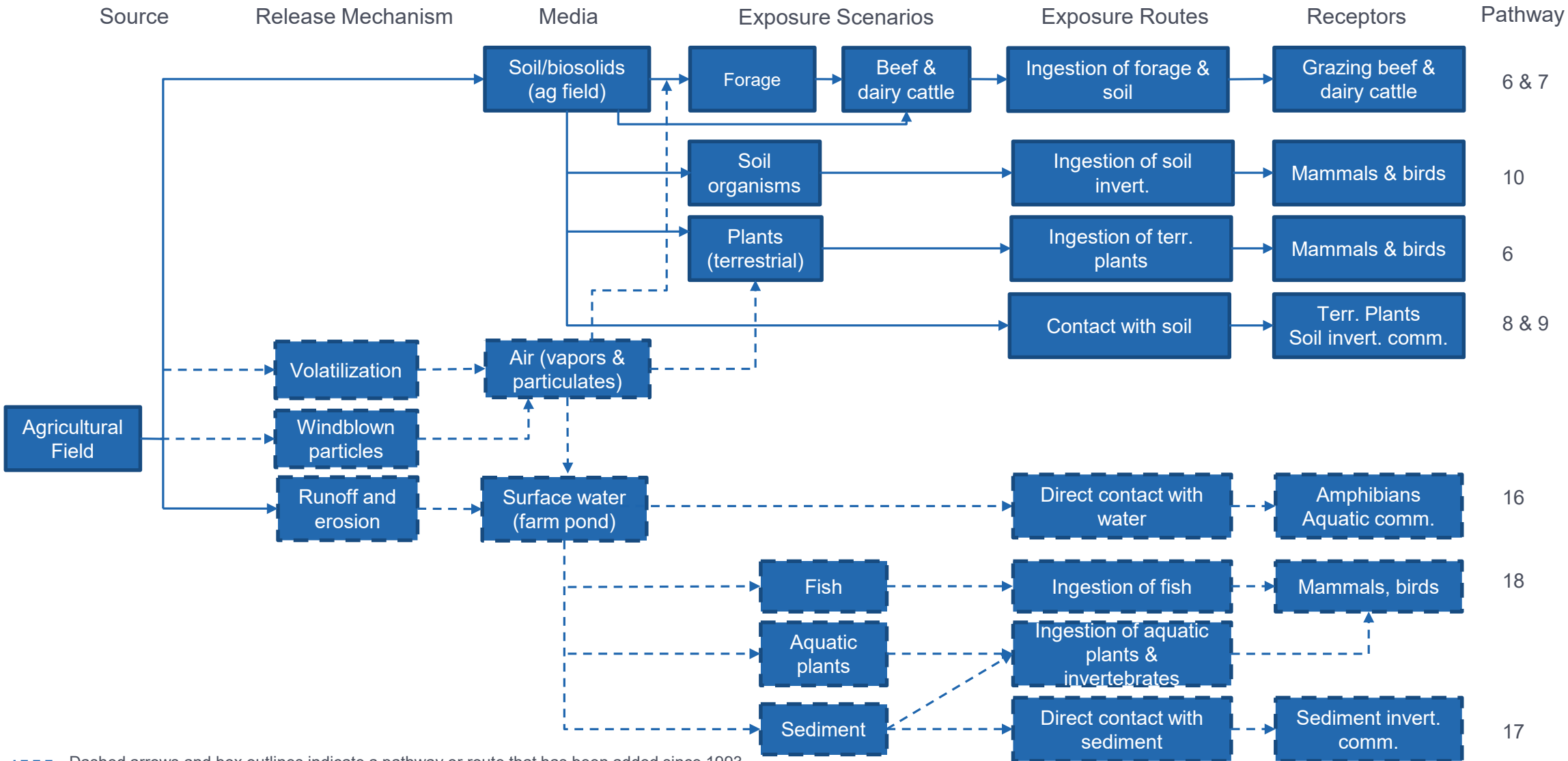
40 CFR Part 503.1: *"(a) Purpose. (1) This part establishes standards, which consist of general requirements, pollutant limits, management practices, and operational standards, for the final use or disposal of sewage sludge generated during the treatment of domestic sewage in a treatment works. Standards are included in this part for sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator."*

Conceptual Model for the Agricultural Land Application Scenario: Human Exposures

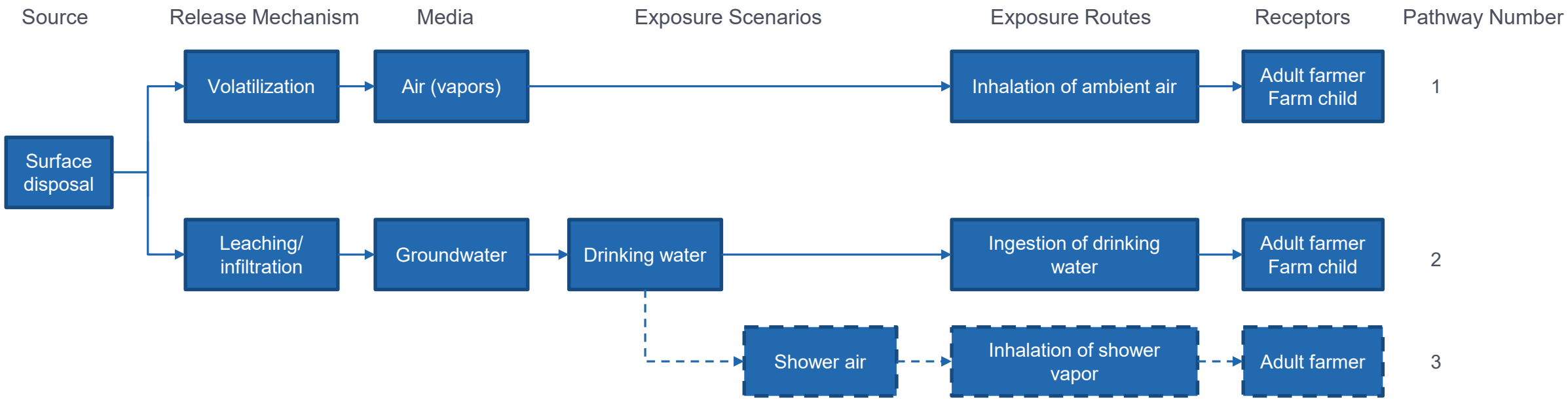


Dashed arrows and box outlines indicate a pathway or route that has been added since 1993.

Conceptual Model for the Agricultural Land Application Scenario: Ecological Exposures

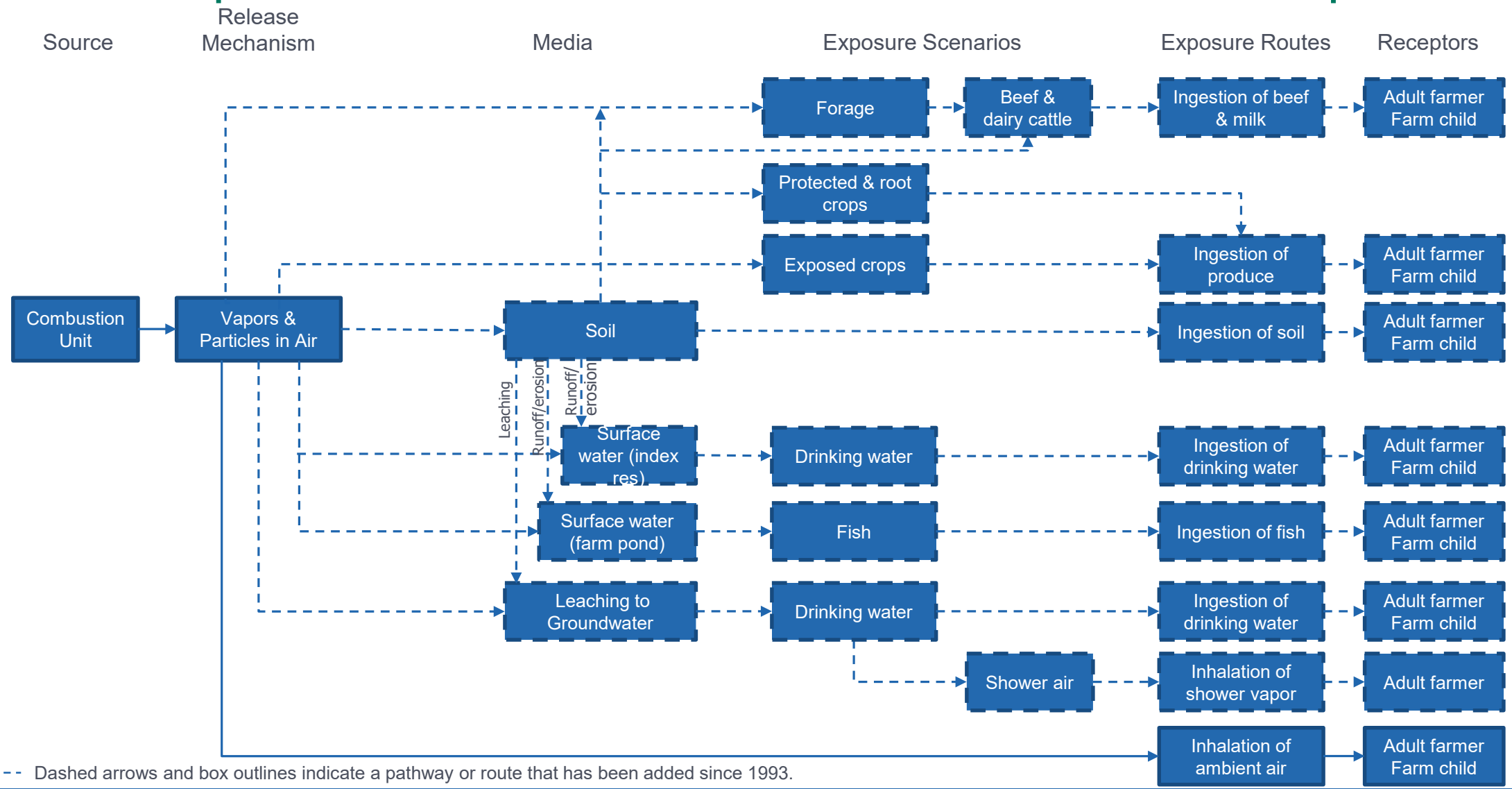


Conceptual Model for Biosolids Surface Disposal: Human Exposures

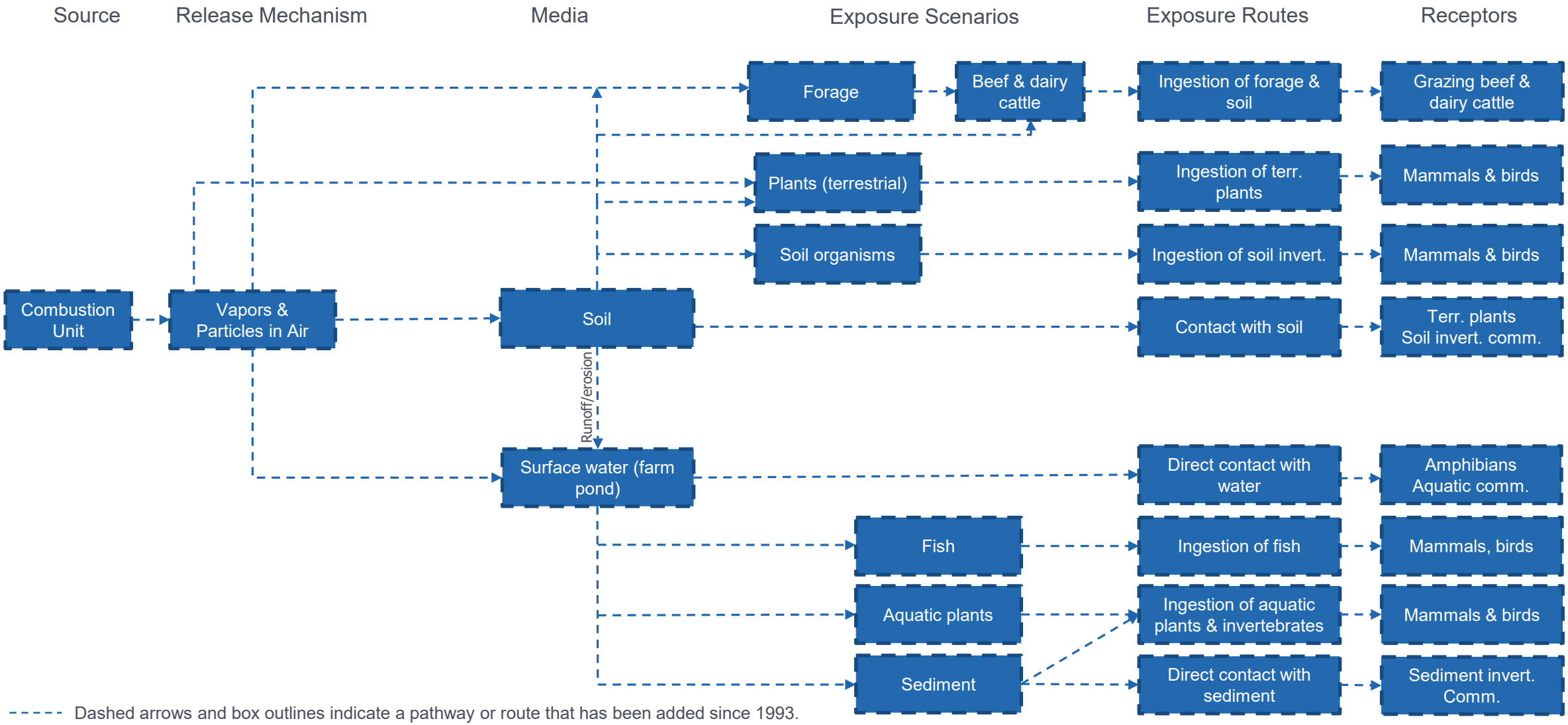


Dashed arrows and box outlines indicate a pathway or route that has been added since 1993.

Conceptual Model for Biosolids Incineration: Human Exposures



Conceptual Model for Biosolids Incineration: Ecological Exposures



Conceptual Models

- Sources of exposure
- Routes of exposure
- Receptors

Questions

1. *Do the conceptual models capture the range of routes of exposure of concern for your state, tribe, or stakeholder group? If not, what is missing?*
2. *Do the conceptual models capture the range of receptors of concern for your state, tribe, or stakeholder group? If not, what is missing?*
3. *Do the conceptual models capture the range of potential health effects of concern for your state, tribe, or stakeholder group? If not, what is missing?*


ANALYSIS PLAN

Toxicity Endpoints

- Biosolids assessment inputs for human health, aquatic life, and aquatic-dependent wildlife will be consistent with other efforts in the EPA Office of Water:
    - Human health effects data support both ambient water criteria for human health and Safe Drinking Water Act regulatory determinations
    - Aquatic life and aquatic-dependent wildlife effects data support ambient water criteria for aquatic life and aquatic-dependent wildlife
- Toxicity endpoints for non-aquatic dependent birds, mammals, terrestrial invertebrates, and terrestrial plants are currently being evaluated by the Biosolids Program

Human Health Toxicity Endpoints

- EPA developed Health Effects Support Documents (HESDs) for PFOA and PFOS Health Advisories that were published in 2016.
    - The HESDs determined the Reference Dose (RfD) and Cancer Slope Factor (CSF).
- As the toxicity literature is constantly evolving, EPA is evaluating new studies and other available information published since 2013.
    - In March of 2020, EPA sought public comment on an annotated bibliography of identified studies as well as the protocol used to identify the relevant data published since 2013 to support efforts for Regulatory Determination 4 under the Safe Drinking Water Act.
    - An initial title and abstract screen has been completed to identify studies with potentially relevant health effects information (*i.e.*, human epidemiology studies, animal toxicity studies, and physiologically based pharmacokinetic [PBPK] studies).

Ecological Toxicity Endpoints

- Ecological toxicity endpoints are currently being evaluated
    - Relevant toxicity studies from peer-reviewed literature were identified through ECOTOX searches (https://cfpub.epa.gov/ecotox/) and reviewed for data quality.
    - Effects on survival, growth, and reproduction are being evaluated.
- EPA is currently working to develop information to support ambient water quality criteria for aquatic life and aquatic-dependent wildlife.
    - EPA plans to begin reviewing ecological toxicity data for their quality and sufficiency for criteria development.

Bioaccumulation Factor (BAF)

- EPA is currently compiling paired fish tissue and water samples that can be used to calculate nationally representative BAFs for trophic levels 2, 3, and 4
    - PFOA and PFOS are ionic organic chemicals
    - National BAFs are calculated from field-measured BAFs or laboratory-measured bioconcentration factors (BCFs)
    - BAFs are normalized by adjusting for the water-dissolved portions of the chemical; this provides a common basis for averaging BAFs from several studies
    - Lipid normalization is not applicable to measured PFOA and PFOS BAF values because these chemicals appear to associate with proteins, not lipids.
    - Kpoc, the partitioning coefficient for particulate organic carbon, for PFOA and PFOS from peer-reviewed sources can be used to normalize measured BAF values
- EPA is also compiling paired tissue and water data that can be used to calculate nationally representative BAFs for other aquatic life and aquatic-dependent wildlife

Modeling Approach

- Currently under development for presentation to the Science Advisory Board in 2021
    - Biosolids Screening Tool for deterministic, screening-level assessment
    - Probabilistic Risk Assessment framework for chemicals that fail at the screening level
- Modeling for biosolids will be based on publicly available, previously peer-reviewed models for leaching, runoff, erosion, air dispersal, and plant uptake to the greatest extent possible
- Approach for PFAS will be consistent, to the extent appropriate, with all other chemical risk assessment for biosolids

Analysis Plan

- Approach for acquiring reliable data
- Models and tools to be used in the analysis

Questions

1. *Are you aware of reliable fate, transport, or toxicity data for various routes of exposure, receptors, or health effects that EPA should know about? If yes, please share.*
2. *Have you used any modeling approaches for PFAS that you would like to share with EPA?*
3. *Is there anything else you would like to share regarding modeling of PFOA and PFOS in biosolids?*

RISK MANAGEMENT AND IMPLEMENTATION

Risk Management and Implementation Considerations

- The EPA risk assessment will characterize risk from biosolids on a national scale
- If EPA determines that PFOA or PFOS in biosolids may adversely affect public health or the environment, risk managers will consider options for numerical limitations and best management practices for these compounds (as there are with current Part 503 pollutant limits)

  Clean Water Act, Section 405(d): If "*it is not feasible to prescribe or enforce a numerical limitation for a pollutant identified under paragraph (2), the Administrator may instead promulgate a design, equipment, management practice, or operational standard, or combination thereof*"

Questions

1. *What considerations or concerns should EPA be aware of during risk management and implementation?*
2. *Do you have any other topics related to risk management or implementation that you would like to raise?*

Thank you

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