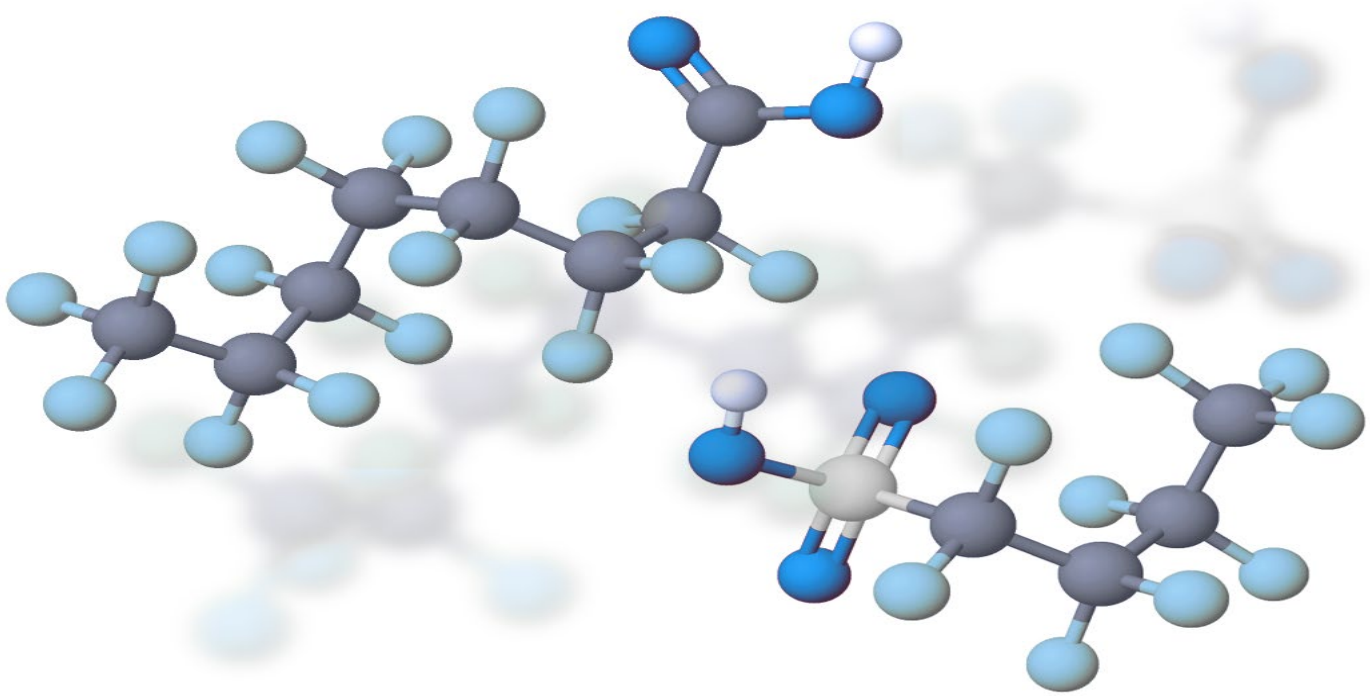
Biosolids PFOA & PFOS Problem Formulation Discussion with Stakeholders

November 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.**

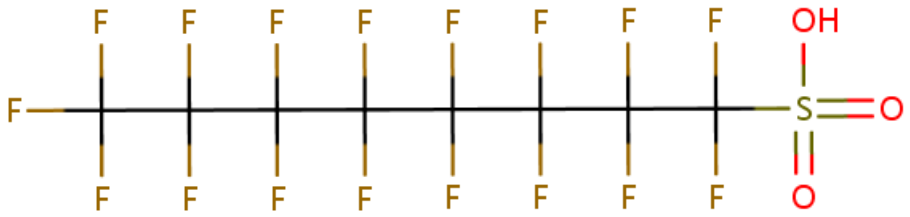
Purpose of the Risk Assessment

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

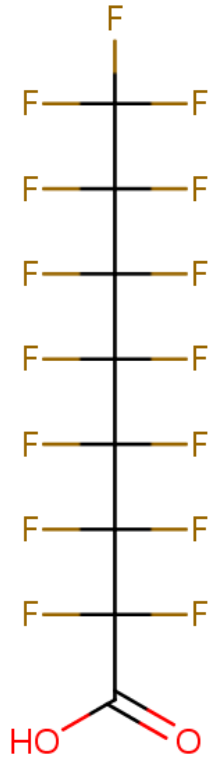
Clean Water Act, Section 405(d): EPA *"shall identify those toxic pollutants which, on the basis of available information on their toxicity, persistence, concentration, mobility, or potential for exposure, may be present in sewage sludge in concentrations which may adversely affect public health or the 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

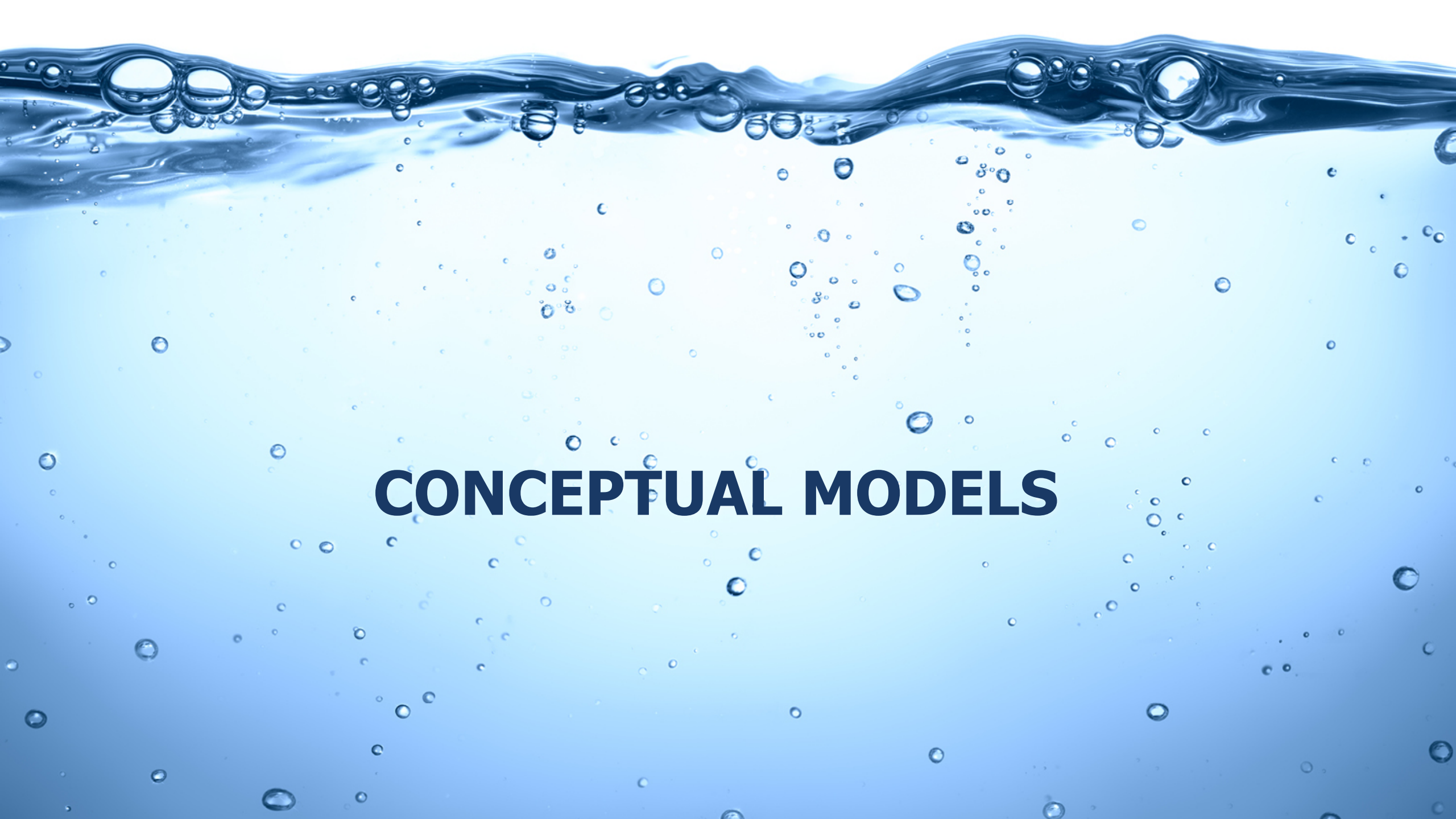
Year Sampled	PFOA (ng/g dry wt)	PFOS (ng/g dry wt)	Reference
2001	12 - 70	308 - 618	Venkatesan, 2013
2004-2007	8 - 68	80 - 219	Sepulvado, 2011
2005	16 - 219	8.2 - 110	Loganathan 2007
2005	18 - 241	<10 - 65	Sinclair, 2006
2006	--	81 - 160	Schultz, 2006
2006-2007	18 - 69	31 - 702	Yu, 2009
2007	20 -128	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 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?*



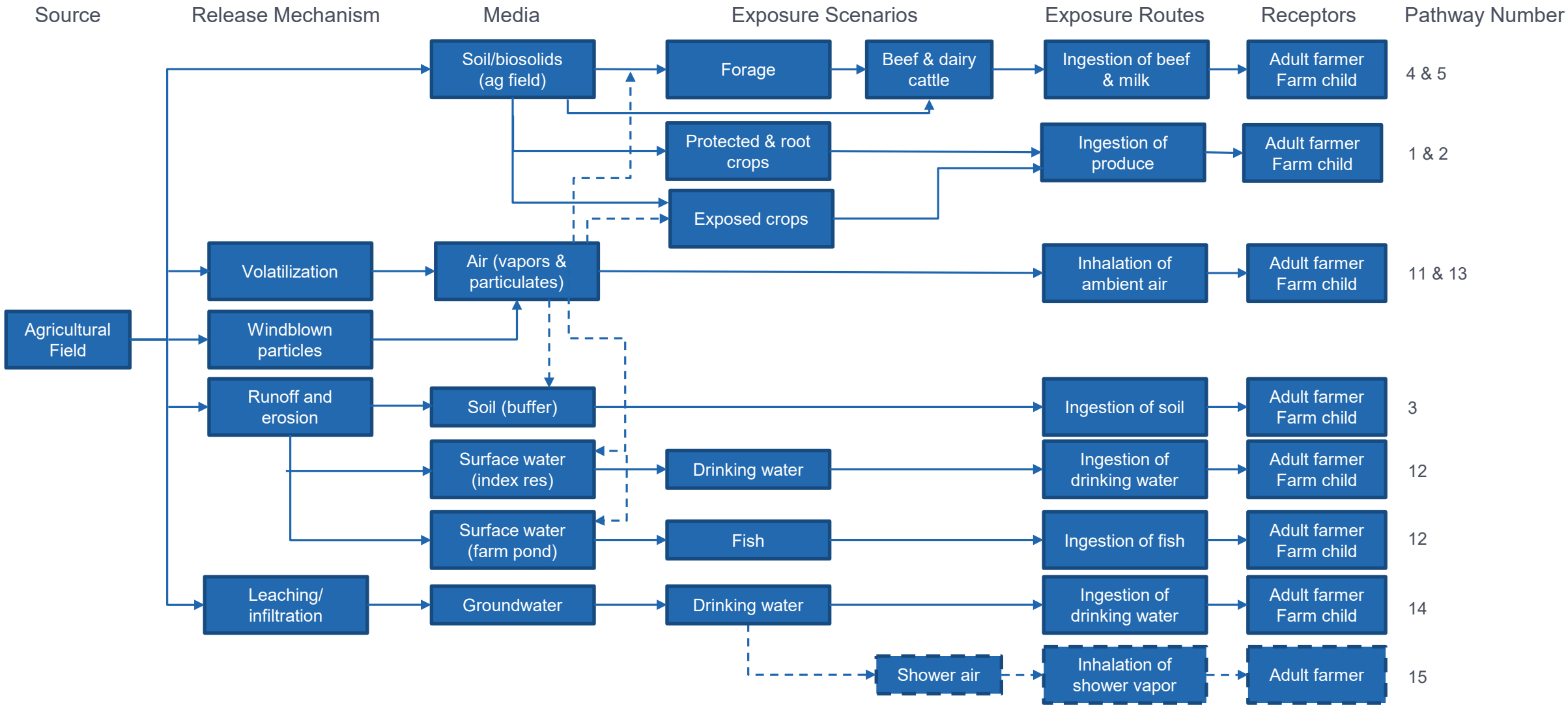
CONCEPTUAL MODELS

Biosolids Use and Disposal Pathways

1. Land Application
2. Surface Disposal
3. Incineration

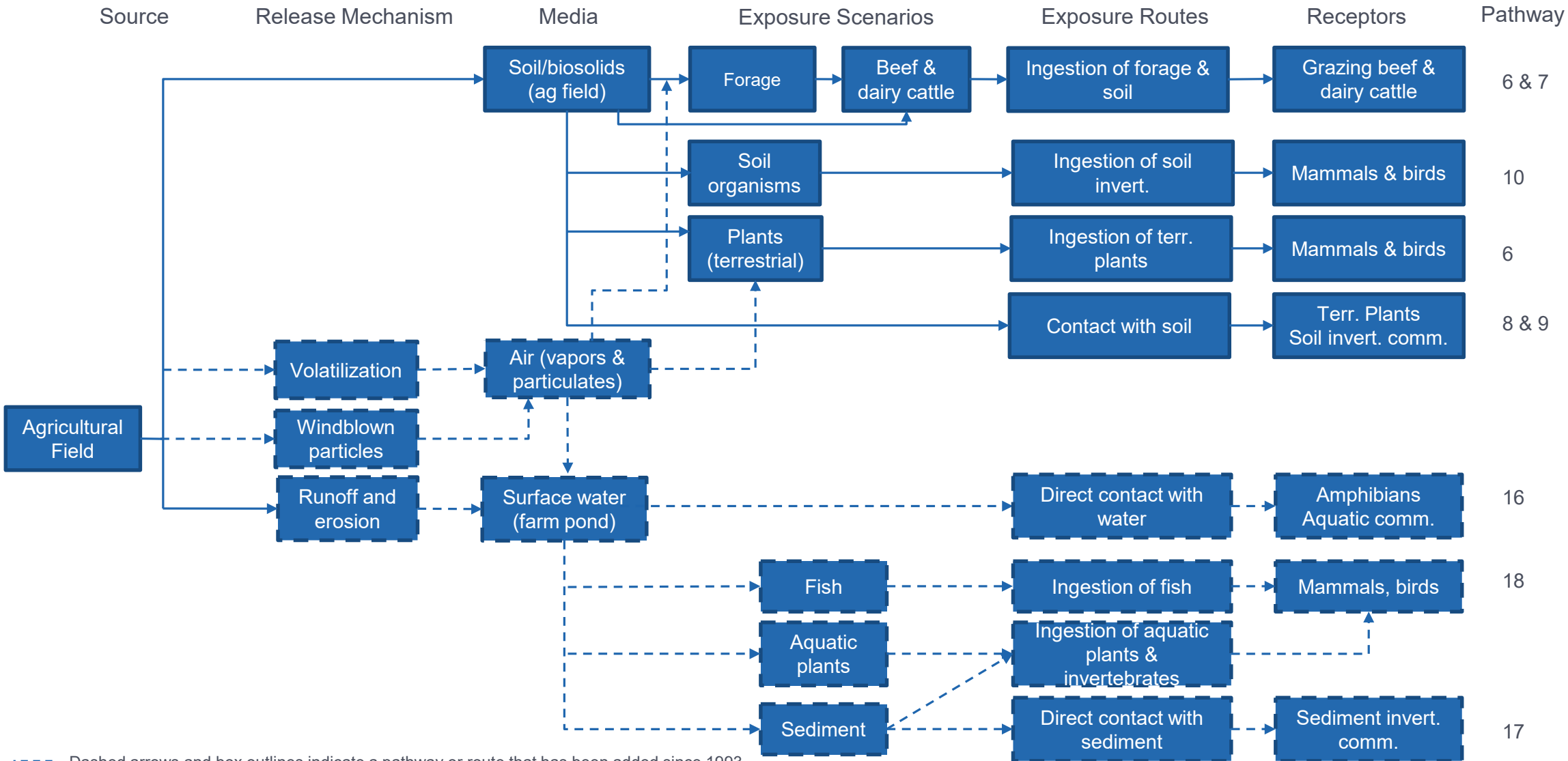
40 CFR Part 503.1: *"(a) Purpose. (1) This part establishes standards, which consist of general requirements, pollutant limits, management practices, and operational standards, for the final use or disposal of sewage sludge generated during the treatment of domestic sewage in a treatment works. Standards 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

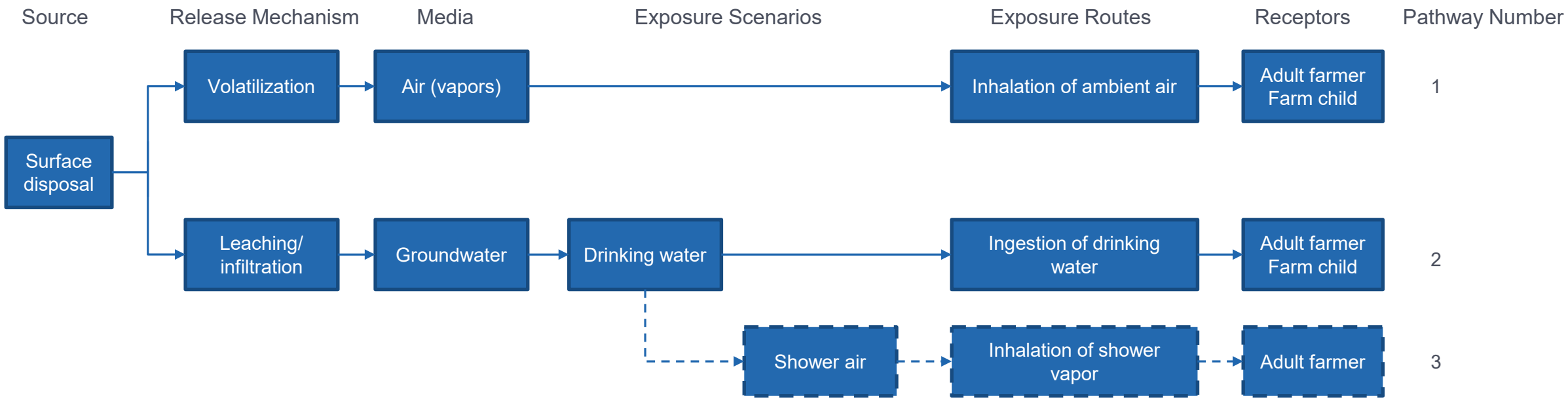


Dashed arrows and box outlines indicate a pathway or route that has been added since 1993.

Conceptual Model for the Agricultural Land Application Scenario: Ecological Exposures

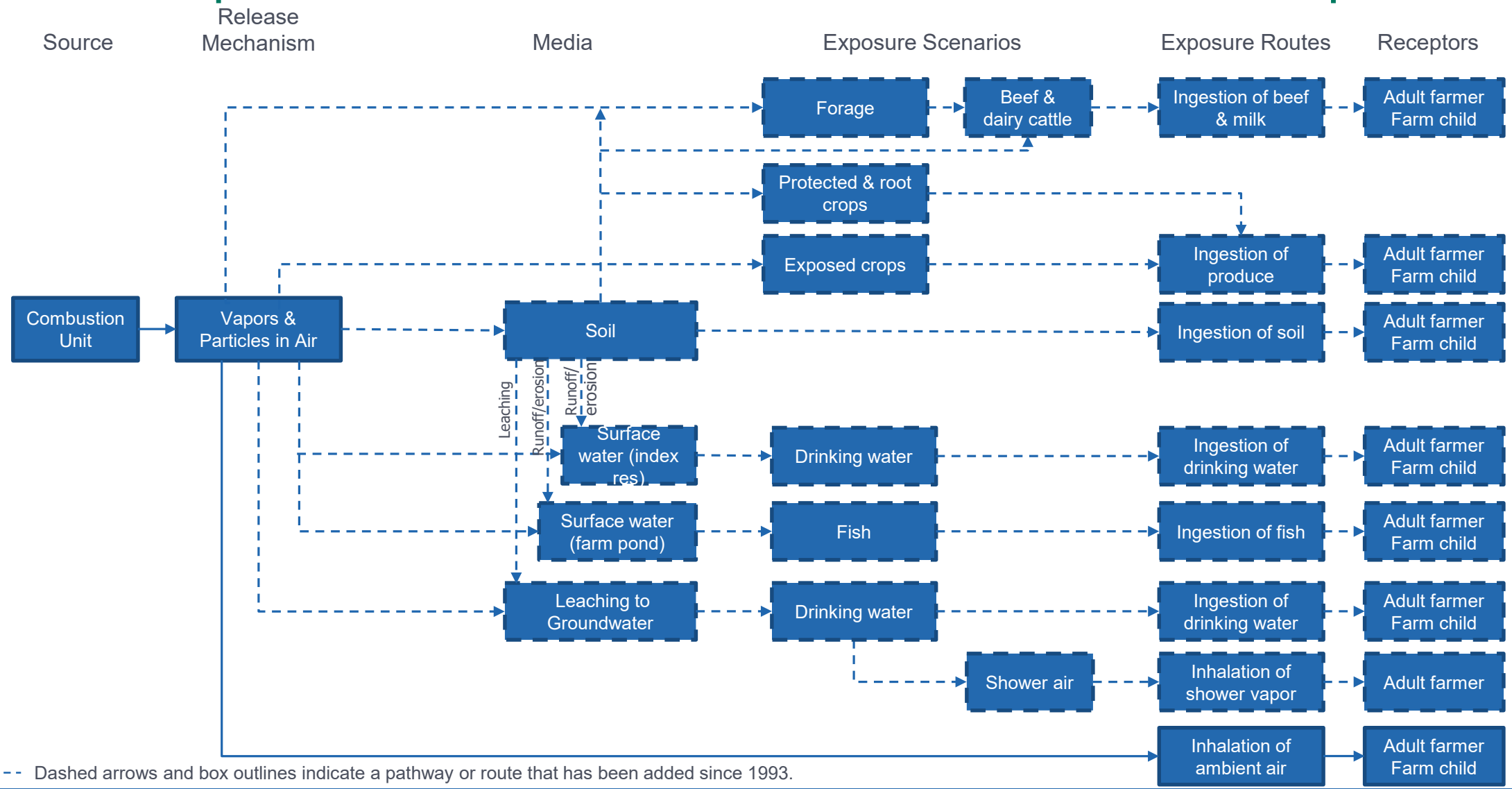


Conceptual Model for Biosolids Surface Disposal: Human Exposures

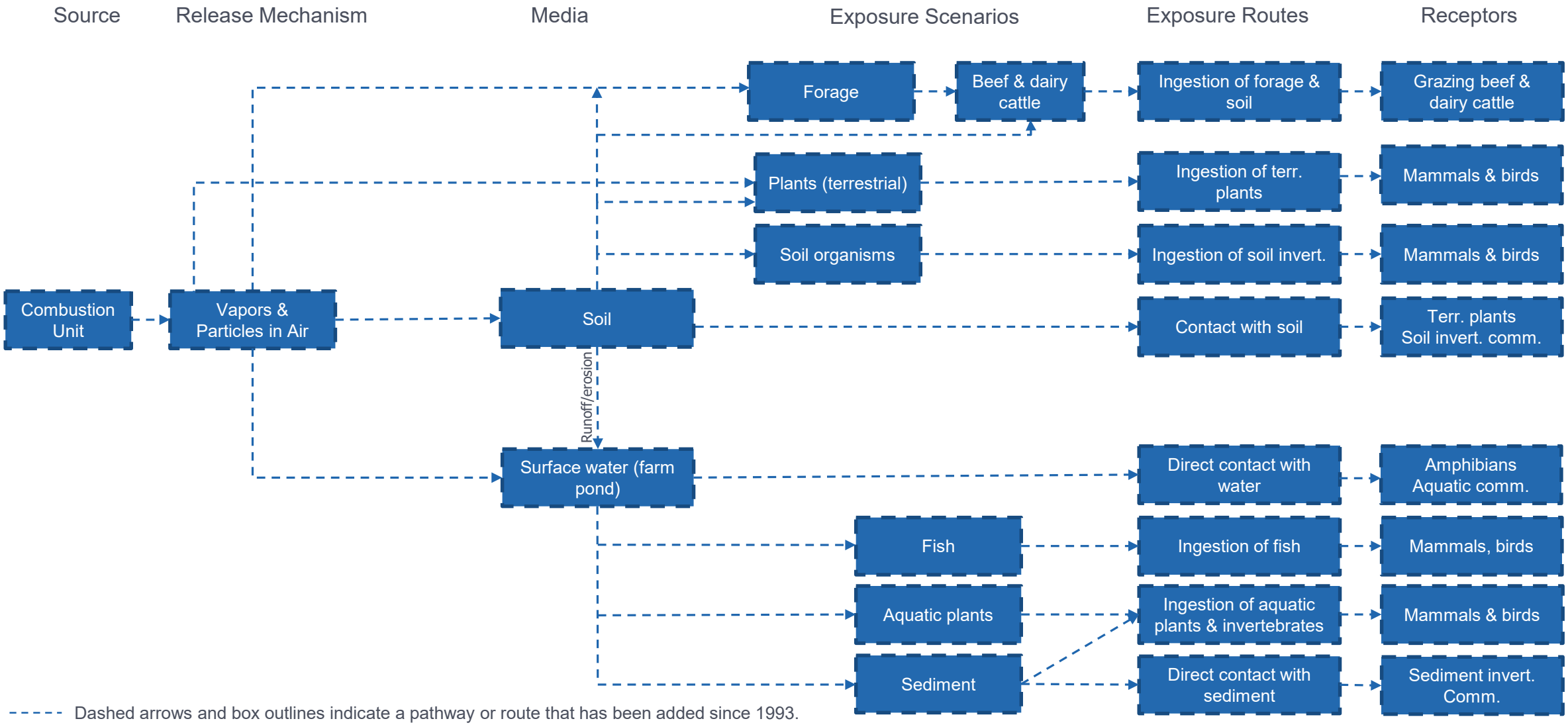


Dashed arrows and box outlines indicate a pathway or route that has been added since 1993.

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

Elyssa Arnold

Risk Assessment Lead, EPA Biosolids Program

arnold.elyssa@epa.gov

202-566-1189