



Biennial Review of 40 CFR Part 503 As Required Under the Clean Water Act Section 405(d)(2)(C)

**Reporting Period
2009 Biennial Review**

Biennial Review of 40 CFR Part 503
As Required Under the Clean Water Act Section 405(d)(2)(C)
Reporting Period Biennial Review 2009

U.S. Environmental Protection Agency
Office of Water
Office of Science and Technology
Health and Ecological Criteria Division
Ecological and Health Processes Branch
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NOTICE

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EXECUTIVE SUMMARY

In 1993, the U.S. Environmental Protection Agency (EPA) promulgated regulations in 40 CFR Part 503 as amended, setting numeric standards for certain metals in sewage sludge prior to being placed on land, on a surface disposal site, or in an incinerator, requiring vector attraction reduction (e.g., reducing birds, rodents and insects) for pathogens, and establishing operational standards for emissions from sewage sludge incinerators. Section 405(d)(2)(C) of the Clean Water Act (CWA) states that EPA shall review (but not necessarily generate a report) the sewage sludge regulations not less often than every two years for the purpose of identifying additional toxic pollutants and promulgating regulations for such pollutants consistent with the requirements of section 405(d).

In fulfilling this commitment for the 2009 Biennial Review Cycle, EPA collected and reviewed publicly available information. The Agency searched databases with articles published in English and in peer reviewed and refereed journals for information on occurrence, fate and transport in the environment, human health and ecological effects, as well as other relevant information for pollutants that may occur in U.S. sewage sludge. If such data are available for pollutants that may occur in sewage sludge, the Agency is able to characterize the potential risk associated with exposure to such pollutants when sewage sludge is applied to land as a fertilizer or soil amendment, placed in a surface disposal site, or incinerated.

The data search identified 49 new pollutants from the potential universe of pollutants, for which some data were available that fit the following criteria: (1) identified in the Targeted National Sewage Sludge Survey (TNSSS; U.S. EPA, 2009) or the open literature as having concentration data for sewage sludge, (2) not currently on EPA's list of potential candidates under evaluation for addition to the Part 503 standards, or (3) not previously regulated or evaluated (e.g., as potentially causing harm to humans or the environment) for sewage sludge. The available exposure or toxicity data are not sufficient at this time for many of the pollutants using current biosolids modeling tools. EPA is in the process of evaluating 26 of these chemicals found in the TNSSS, however those assessments have not yet been completed. We will continue this work subject to availability of resources and overall program priorities. At this time EPA has

not identified additional toxic pollutants for regulation under Section 405(d)(2)(C) of the CWA.

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Introduction

This document summarizes the U.S. Environmental Protection Agency's (EPA) activities related to the 2009 biennial review of pollutants pursuant to the Clean Water Act (CWA) Section 405(d)(2)(C). That section requires EPA to review existing sewage sludge regulations at least every two years to identify additional pollutants for possible regulation. The biennial review covered by this report summary, the 2009 Biennial Review, obtained sewage sludge-related literature through July 2009. Published data after this date will be considered in the 2011 Biennial Review. This document summarizes the analysis of that literature (a Technical Memorandum contractor summary is included in Attachment A). EPA often uses the term "biosolids" interchangeably with "sewage sludge," which is defined in the regulations and used in the statute.

History of the Standards for Use or Disposal of Sewage Sludge

In Section 405 of the CWA, Congress set forth a comprehensive program designed to reduce potential health and environmental risks associated with using or disposing of sewage sludge. Under Section 405(d), EPA establishes numeric limits and management practices that protect public health and the environment from the reasonably anticipated adverse effects of chemical and microbial pollutants in sewage sludge. Under Section 405(d), it is unlawful for any person to dispose of sewage sludge from a publicly owned treatment works (POTWs) or any other treatment works treating domestic sewage for any use for which regulations have been established pursuant to Section 405(d), except in accordance with those regulations.

On February 19, 1993, EPA identified pollutants which, on the basis of available information on their toxicity, persistence, concentration, mobility, or potential for exposure, were present in sewage sludge in concentrations which may adversely affect public health or the environment. At that time, the Agency promulgated regulations, 40 CFR Part 503 *Standards for the Use or Disposal of Sewage Sludge*, specifying acceptable management practices, numeric standards for eleven metals (see Table 1), and operational standards for microbial organisms (58 *FR* 9248).

The 1993 rule established requirements for the final use or disposal of sewage sludge when it is: (1) applied to land as a fertilizer or soil amendment; (2) placed in a surface disposal site, including sewage sludge-only landfills; or (3) incinerated. These requirements apply to publicly and privately owned treatment works that generate or treat domestic sewage sludge and to anyone who manages sewage sludge. The rule also requires monitoring, record keeping, and reporting of specific information regarding sewage sludge management.

Table 1: Metals Regulated in 40 CFR 503

Metal	Land Application	Incineration ²	Surface Disposal
Arsenic	X	X	X
Beryllium		X	
Cadmium	X	X	X
Chromium	X ¹	X	X
Copper	X		
Lead	X	X	X
Mercury	X	X	
Molybdenum	X ¹		
Nickel	X	X	X
Selenium	X ¹		
Zinc	X		

^{1/} Minor amendments published in 1994 and 1995 improved clarity and responded to the results of judicial review resulting in changes in land application limits for chromium (deleted all limits; 60 FR 54764), molybdenum (deleted limits in Tables 2, 3, and 4 of Section 503.13; 59 FR 9095), and selenium (revising the selenium value for Table 3 of Section 503.13; 60 FR 54764)

^{2/} Beryllium and Mercury emissions are regulated as limits to air emissions either by monitoring the exhaust air from the incinerator or the ambient air around the incinerator. In either case, the concentration in the air must meet the National Emission Standards for Hazardous Air Pollutants (NESHAPs, 40 CFR Part 61). Individual facility limits are based on unit performance calculations for Arsenic, Cadmium, Chromium, Lead, and Nickel. Operational standards include monitoring total hydrocarbons (THC) or carbon monoxide (CO) not to exceed 100 ppm by volume to represent all organic compounds in the exhaust gas that are covered by the Part 503 Rule. See Subpart E, Section 503.43 for other incineration requirements.

Biennial Reviews

Section 405(d)(2)(C) of the CWA requires the Agency to review from time to time, but not less often than every 2 years (i.e., biennial reviews), the regulations for the purpose of identifying additional toxic pollutants and promulgating regulations for such pollutants (the Agency uses the term pollutant as defined in the CWA). The purpose of reviewing information on pollutants, or potential pollutants, is to assess the availability and sufficiency of the data to conduct exposure and hazard assessments. Such exposure and hazard assessments, where sufficient data exist, allow the Agency to determine the potential for harm to public health or the environment following use or disposal of sewage sludge. To inform the exposure and hazard assessments of pollutants in sewage sludge, EPA typically uses models that require the following data:

- Toxicity to human and ecological receptors (e.g., toxicity defined in terms of reference dose, reference concentrations, cancer slope factor, lethal dose, lethal concentration, or chronic endpoints related to fecundity).
- Concentration data in sewage sludge. Both the ability to detect a given pollutant in sewage sludge and the concentrations at which that pollutant is present are highly dependent on the existence of analytical methods for that pollutant in the sewage sludge matrix.
- Fate and transport data for pollutants that may be present in sewage sludge. These data are necessary for assessing exposure. Examples of chemical and physical properties that are considered depending on the nature of a given pollutant in sewage sludge include:

Parameter
Molecular weight
Solubility
Vapor pressure
Henry's law constant
Soil-water partitioning coefficient
Soil adsorption coefficient (K_d and K_{oc})
Degradation rates in various media
Log octanol-water partition coefficient (Log K_{ow})
Diffusivity in air and water
Air-to-plant transfer factor
Root uptake factor for above ground vegetation
Root concentration factor
Bioconcentration factors for animal products (e.g., meat and milk)

The Agency evaluates the sufficiency of such data for pollutants having acceptable analytical methods, source concentration values, human health and ecological toxicity data, and data on environmental fate to support potential rulemaking under 40 CFR Part 503 (i.e., the development of numeric standards).

2009 Biennial Review

EPA has conducted Biennial Reviews in 2003, 2005, and 2007. This document presents the 2009 Biennial Review. In conducting the 2009 Biennial Review, EPA collected and reviewed publicly available information on pollutants to evaluate potential harm to human health or the environment following use or disposal of sewage sludge.

Human Health Assessment

To determine if data are available to evaluate human health risks, EPA conducted a literature search for information published from October 2007 through July 2009. EPA searched databases and the published literature for information such as occurrence, fate and transport in the environment, and human health for pollutants in U.S. sewage sludge. Searches included the following: PubMed, TOXLINE, and the Environmental Sciences and Pollution Management Database.

For biosolids human health risk evaluations, EPA used established procedures and relied on available Integrated Risk Information System (IRIS) and the Office of Pesticide Programs (OPP) established oral human health acute or chronic toxicity data for environmental contaminants and pesticides used by the Agency for risk assessment and risk management activities. For future activities involving biosolids risk evaluation (e.g., future biennial reviews and evaluation of TNSSS pollutants), and because toxicity data on pharmaceuticals and personal care products are seldom available through IRIS or OPP, EPA plans to utilize data available from other sources (e.g., the Food and Drug Administration Center for Veterinary Medicine, the Joint FAO/WHO Expert Committee on Food Additives, the FDA Center for Drug Evaluation and Research, and the Agency for Toxic Substances and Disease Registry of the U.S. Department of Health and Human Services) to evaluate health risks of these and other contaminants going forward.

Ecological Assessment

EPA conducted a literature search for information published from October 2007 through July 2009 and searched databases and the published literature to capture available information necessary for ecological risk evaluations (e.g., occurrence, fate and transport in the environment, and ecological effects) for pollutants in U.S. sewage sludge. The Agency used articles published in English in peer-reviewed journals, databases such as ECOTOX, Aquatic Sciences and Fisheries Abstracts, Biological Sciences Database, and the Environmental Sciences and Pollution Management Database, as well data for eco-toxicity benchmarks (e.g., the recent EPA Ecological Soil Screening Levels for certain metals for use in assessments under Superfund).

Results of the 2009 Biennial Review

The Agency's search of these databases and the open literature for articles published since the 2007 Biennial Review (EPA-822-R-09-005) identified information for 49 pollutants (listed in Tables 2 and 3). Some pollutants (e.g., triclosan and azithromycin) have been reported in previous biennial reviews. EPA may revisit previously evaluated pollutants, especially if literature searches of bibliographic databases reveal newer data. The Agency evaluated the availability and acceptability of data addressing toxicity to human and ecological receptors, pollutant concentrations in sewage sludge based on analytical methods, physical and chemical properties, and fate and transport in the environment in order to be able to conduct exposure and hazard assessments.

Two criteria were established for selecting a pollutant for an exposure and hazard evaluation if relevant exposure data were available: 1) the pollutant has human health or ecological toxicity values (e.g., studies that are adequate for evaluating hazards following acute or chronic exposure) and (2) the pollutant concentrations in U.S. sewage sludge are adequate (i.e., data are considered adequate when sufficient details are provided regarding sampling, handling, and analysis) based on suitable analytical methodology for detecting and quantifying pollutant concentrations (i.e., analytical methodology are acceptable when the processes and techniques have been independently replicated and / or validated, and written standard operating procedures exist).

The Agency divided the list of 49 identified pollutants into two major groups (i.e., those with human health benchmarks and those without human health benchmarks):

1. Table 2 lists fourteen of the forty-nine chemicals identified in the 2009 Biennial Review that have human health toxicity values (e.g., toxicity defined in terms of reference dose, reference concentrations, or cancer slope factor).

Table 2. Pollutants Evaluated During the 2009 Biennial Review With Human Health Benchmarks

Constituent Name	CAS Number	Class
17 β -Estradiol	50-28-2	hormone
Chlortetracycline	57-62-5	antibiotic
Decabromodiphenyl ether	1163-19-5	PBDE
Erythromycin	114-07-8	antibiotic
Lincomycin	154-21-2	antibiotic
Oxytetracycline	6153-64-6	antibiotic
Pentabromodiphenyl ether	32534-81-9	PBDE
Progesterone	57-83-0	hormone
Sulfamethazine	57-68-1	antibiotic
Testosterone	58-22-0	hormone
Tetracycline	60-54-8	antibiotic
Triclosan	3380-34-5	antimicrobial
Trimethoprim	738-70-5	antibiotic
Virginiamycin	21411-53-0	antibiotic

EPA is in the process of evaluating the 14 pollutants listed in Table 2, as they were also found in the Targeted National Sewage Sludge Survey (U.S. EPA, 2009).

Critical information gaps for chemicals listed in Table 2 are identified in Attachment A and include ecological effects endpoints, physical and chemical properties (e.g., diffusivity in water, aerobic biodegradation in soil and water, and anaerobic biodegradation in sediment), and bioconcentration and biotransfer factors.

2. Table 3 lists 35 of the 49 pollutants in sewage sludge for which the search did not identify IRIS or OPP human toxicity values. These pollutants were picked up when the literature search found other available data. EPA is in the process of evaluating 12 of the pollutants listed in Table 3, as they were also found in the Targeted National Sewage Sludge Survey (U.S. EPA, 2009). Critical information gaps for chemicals listed in Table 3 are identified in Attachment A and include ecological effects endpoints, physical and chemical properties (e.g., diffusivity in water, aerobic biodegradation in soil and water, and anaerobic biodegradation in sediment), and bioconcentration and biotransfer factors.

Table 3. List of Pollutants for which Human Health Benchmark Data Are Lacking

Constituent Name	CAS Number	Class
Azithromycin	83905-01-5	antibiotic
Caffeine	58-08-2	other drug
Carbamazepine	298-46-4	pharmaceutical
Ciprofloxacin	85721-33-1	antibiotic
Clarithromycin	81103-11-9	antibiotic
Diltiazem	42399-41-7	pharmaceutical
Doxycycline	564-25-0	antibiotic
Estrone	53-16-7	hormone
Galaxolide (HHCB)	1222-05-5	fragrance
Gemfibrozil	25812-30-0	pharmaceutical
Methamphetamine	537-46-2	pharmaceutical
Methylenedioxymethamphetamine, 3,4-	42542-10-9	pharmaceutical
Nonylphenol	104-40-5	surfactant
Norfloxacin	70458-96-7	antibiotic
Sulfadimethoxine	723-46-6	antibiotic
Tonalide (AHTN)	21145-77-7	fragrance
Triclocarban	101-20-2	disinfectant
Adenovirus	Not applicable	virus
<i>Aeromonas</i> spp.	Not applicable	bacteria
<i>Bacteroides fragilis</i> phage	Not applicable	bacteriophage (viral indicator)
<i>Clostridia</i>	Not applicable	bacteria
<i>Clostridium perfringens</i>	Not applicable	bacteria
Enterococci	Not applicable	bacterial indicator
Enterovirus	Not applicable	virus
<i>Escherichia coli</i> (<i>E. coli</i>)	Not applicable	bacteria
Fecal streptococci	Not applicable	bacteria
F-RNA phage	Not applicable	bacteriophage (viral indicator)
F-specific phage	Not applicable	bacteriophage (viral indicator)
Giardia	Not applicable	parasite
HAV (Human Adenoviruses)	Not applicable	virus
<i>Listeria monocytogenes</i>	Not applicable	bacteria
<i>Listeria</i> spp.	Not applicable	bacteria
<i>Salmonella senftenberg</i>	Not applicable	bacteria
Somatic coliphage	Not applicable	bacteriophage
Total coliforms	Not applicable	bacterial indicator

As its first priority, EPA is in the process of evaluating 26 of the 49 pollutants identified in this 2009 biennial review, as they were also found in the Targeted National Sewage Sludge Survey (U.S. EPA, 2009). Those assessments have not been completed at this time, given available resources and other priorities. There are significant data gaps (environmental properties, human health and eco-toxicity values, and acceptable concentration data in sewage sludge) for the remaining 23 pollutants that limit the use of EPA's current biosolids model for risk assessment at this time. Thus, EPA has not identified any additional toxic pollutants during its 2009 Biennial Review for potential regulation.

The Agency will continue to assess the availability of sufficient information for these 49 pollutants and other pollutants identified during the biennial review activities pursuant to section 405(d)(2)(C) of the CWA.

Additional Information

For more information about EPA's Biosolids Program, contact Rick Stevens in the Health and Ecological Criteria Division, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460 (telephone: 202-566-1135 or e-mail: stevens.rick@epa.gov).

Reference

U.S. EPA, 2009. Targeted National Sewage Sludge Survey Sampling and Analysis Report. Office of Water, Washington, DC. EPA-822-R-08-016. January 2009.
http://water.epa.gov/scitech/wastetech/biosolids/upload/2009_01_15_biosolids_tnss-tech.pdf

Attachment A

Technical Memorandum

Report on Pollutants' Database and Suitability

Technical Memorandum
Report on Pollutants' Database and Suitability

U.S. Environmental Protection Agency
Office of Water
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Introduction

The following technical memorandum identifies chemical and microbial pollutants in U.S. sewage sludge between 2007 and 2009, and provides EPA with information for evaluating the suitability for modeling and potential rulemaking for these pollutants.

1 *Data Search*

The search for new data primarily utilized the strategy developed under previous biennial review efforts; results from bibliographic databases were limited to articles published in English in refereed journals. The bibliographic databases included Pub Med, Science Citation Index Expanded, and Environmental Sciences & Pollution Management. Publications from October 2007 to July 2009 were sought. The data search key words included a combination of:

Topic/Keyword: sewage sludge, biosolids, treated sewage, sludge treatment, land application, farm, agriculture, soil

AND

Topic/Keyword: pollutants, toxicants, pharmaceuticals, antibiotics, steroids, hormones, pathogens, microbial, *Salmonella*

Using this search strategy, 110 articles were identified as potential sources of information on chemical and microbial pollutants in biosolids.

From the 110 articles, 10 articles shown in Attachment A were identified as potential sources of information on chemical and microbial pollutants in biosolids¹. Many studies were off-topic (e.g., non-biosolids media, non-US data, or not municipal waste) or addressed pollutants that have been previously modeled; these studies were omitted from consideration and are not included in Attachment A. Topics of excluded studies included concentration data in other media (e.g., wastewater effluent, surface waters, and soil), non-U.S. data, and not municipal waste (e.g., industrial, agricultural). The pollutants identified in these articles were divided into two major groups:

1. Pollutants that have not previously been evaluated but have readily available health benchmarks, and
2. Pollutants that have been identified in recent studies on biosolids and for which human health benchmarks were not identified in a major reference (i.e., IRIS or EPA's Office of Pesticides Program).

¹

Note that Attachment A includes abstracts when available.

2 Identification of Additional Pollutants in U.S. Sewage Sludge

2.1 Pollutants with Health Benchmarks

Table 1 lists the chemicals (n=14) with health toxicity data that fit the following criteria: (1) identified in the Targeted National Sewage Sludge Survey (TNSSS 2009) or the open literature, (2) not currently on EPA's list of potential candidates for addition to the Part 503 standards, and (3) not previously regulated or evaluated for sewage sludge. The chemicals are also identified by analyte groups defined by similarity in structure and typical uses, as appropriate.

Table 1. List of Pollutants with Health Benchmarks

Constituent Name	CASRN	IRIS/OPP?	Class
17 β -Estradiol	50-28-2		hormone
Chlortetracycline	57-62-5		antibiotic
Decabromodiphenyl ether	1163-19-5	IRIS	PBDE
Erythromycin	114-07-8		antibiotic
Lincomycin	154-21-2		antibiotic
Oxytetracycline	6153-64-6	OPP	antibiotic
Pentabromodiphenyl ether	32534-81-9	IRIS	PBDE
Progesterone	57-83-0		hormone
Sulfamethazine	57-68-1		antibiotic
Testosterone	58-22-0		hormone
Tetracycline	60-54-8		antibiotic
Triclosan	3380-34-5	OPP	antimicrobial
Trimethoprim	738-70-5		antibiotic
Virginiamycin	21411-53-0		antibiotic

Tables 1.1 and 1.2 provide the parameters needed to support modeling. The data collection efforts focused on the following exposure pathways: soil ingestion/contact; groundwater ingestion; surface water contact (including sediment); produce ingestion; animal ingestion; and fish ingestion. Tables 1.3 and 1.4 identify when parameters values were available from EPA's primary data sources.

Table 1.1: Physical and Chemical Property Abbreviations.

Abbreviation	Physical/Chemical Properties
Density	Density
Da	Diffusivity in air
Dw	Diffusivity in water
HLC	Henry's law constant
$k_{\text{aer-soil}}$	Aerobic biodegradation rate in soil
$k_{\text{aer-sw}}$	Aerobic biodegradation rate in surface water
$k_{\text{anaer-sed}}$	Anaerobic biodegradation rate in sediment
Kd	Sorption distribution coefficient
k_h	Hydrolysis rate
K_{oc}	Organic carbon-water distribution coefficient
K_{ow}	Octanol-water distribution coefficient
MP	Melting point
MW	Molecular weight
P_c	Critical pressure
pKa	Dissociation constant, acid
Sol	Water solubility
T_b	Boiling point
T_c	Critical temperature
VP	Vapor pressure

Table 1.2: Bioconcentration and Biotransfer Factor Abbreviations.

Abbreviation	Bioconcentration and Biotransfer Factors
BCF_beef	Bioconcentration factor in beef
BCF_eggs	Bioconcentration factor in eggs
BCF_fish	Bioconcentration factor in fish
BCF_milk	Bioconcentration factor in milk
BCF_pork	Bioconcentration factor in pork
BCF_poultry	Bioconcentration factor in poultry
BrExfruit	Plant-soil bioconcentration factor in exposed fruit
BrExveg	Plant-soil bioconcentration factor in exposed vegetables
BrForage	Plant-soil bioconcentration factor in forage
BrGrain	Plant-soil bioconcentration factor in grain
BrProfruit	Plant-soil bioconcentration factor in protected fruit
BrProveg	Plant-soil bioconcentration factor in protected vegetables
BrRoot	Plant-soil bioconcentration factor for roots
BrSilage	Plant-soil bioconcentration factor for silage
Bs	Bioavailability of contaminant on the soil relative to vegetation
RCF	Root concentration factor

Table 1.3: Summary of Physical and Chemical Properties for 14 pollutants with human health toxicity values (see Table 2).

Analyte	CASRN	Density	Da	Dw	HLC	Kd	kh	Koc	LogK _{ow}	k _{anaer-sed}	k _{aer-soil}	k _{aer-sw}	MP	MW	Pc	pKa	Sol	Tb	Tc	VP
Decabromodiphenyl ether (BDE-209)	1163-19-5	✓			✓			✓	✓				✓	✓			✓	✓		✓
Pentabromodiphenyl ether (BDE-99)	60348-60-9	✓			✓	✓		✓	✓				✓	✓			✓	✓		✓
Chlortetracycline	57-62-5				✓			✓	✓					✓		✓	✓			✓
Erythromycin	114-07-8				✓			✓	✓					✓		✓	✓			✓
lincomycin	154-21-2				✓			✓	✓					✓		✓	✓			✓
Oxytetracycline	79-57-2	✓			✓			✓	✓				✓	✓		✓	✓			✓
Sulfamethazine	57-68-1				✓	✓	✓	✓	✓				✓	✓		✓	✓			✓
Tetracycline	60-54-8				✓	✓			✓	✓	✓			✓		✓	✓			✓
Triclosan	3380-34-5				✓	✓		✓	✓				✓	✓		✓	✓	✓		✓
Trimethoprim	738-70-5				✓	✓		✓	✓					✓		✓	✓			✓
17β-Estradiol	50-28-2				✓	✓		✓	✓				✓	✓		✓	✓	✓		✓
Progesterone	57-83-0	✓							✓				✓	✓		✓	✓			✓
Testosterone	58-22-0				✓	✓		✓	✓				✓	✓		✓	✓			✓
Virginamycin	11006-76-1													✓						

Table 1.4: Summary of Bioconcentration and Biotransfer Factors per Chemical

Analyte	BCF beef	BCF eggs	BCF milk	BCF pork	BCF poultry	BCF fish	BrEx fruit	BrEx veg	Br Forage	Br Grain	BrPro fruit	BrPro veg	Br Root	Br Silage	Bs	RCF
Decabromodiphenyl ether (BDE-209)						✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Pentabromodiphenyl ether (BDE-99)						✓										
Chlortetracycline																
Erythromycin																
Lincomycin																
Oxytetracycline																
Sulfamethazine																
Tetracycline																
Triclosan						✓										
Trimethoprim																
17β-Estradiol						✓										
Progesterone																
Testosterone																
Virginamycin																

2.2 Pollutants without Human Health Benchmarks

Table 2 lists 35 additional pollutants of concern (e.g., pharmaceuticals, hormones) in sewage sludge for which our search failed to identify human health benchmarks in EPA-approved sources.

Table 2. List of Pollutants for which Health Benchmarks were not Identified

Constituent Name	CASRN	Class
Azithromycin	83905-01-5	antibiotic
Caffeine	58-08-2	other drug
Carbamazepine	298-46-4	pharmaceutical
Ciprofloxacin	85721-33-1	antibiotic
Clarithromycin	81103-11-9	antibiotic
Diltiazem	42399-41-7	pharmaceutical
Doxycycline	564-25-0	antibiotic
Estrone	53-16-7	hormone
Galaxolide (HHCB)	1222-05-5	fragrance
Gemfibrozil	25812-30-0	pharmaceutical
Methamphetamine	537-46-2	pharmaceutical
Methylenedioxymethamphetamine, 3,4-	42542-10-9	pharmaceutical
Nonylphenol	104-40-5	surfactant
Norfloxacin	70458-96-7	antibiotic
Sulfadimethoxine	723-46-6	antibiotic
Tonalide (AHTN)	21145-77-7	fragrance
Triclocarban	101-20-2	disinfectant
Adenovirus	Not applicable	virus
<i>Aeromonas</i> spp.	Not applicable	bacteria
<i>Bacteroides fragilis</i> phage	Not applicable	bacteriophage (viral indicator)
<i>Clostridia</i>	Not applicable	bacteria
<i>Clostridium perfringens</i>	Not applicable	bacteria
Enterococci	Not applicable	bacterial indicator
Enterovirus	Not applicable	virus
<i>Escherichia coli</i> (<i>E. coli</i>)	Not applicable	bacteria
Fecal streptococci	Not applicable	bacteria
F-RNA phage	Not applicable	bacteriophage (viral indicator)
F-specific phage	Not applicable	bacteriophage (viral indicator)
Giardia	Not applicable	parasite
HAV (Human Adenoviruses)	Not applicable	virus
<i>Listeria monocytogenes</i>	Not applicable	bacteria
<i>Listeria</i> spp.	Not applicable	bacteria
<i>Salmonella senftenberg</i>	Not applicable	bacteria
Somatic coliphage	Not applicable	bacteriophage
Total coliforms	Not applicable	bacterial indicator

REFERENCES

Bommanna, L., M. Phillips, H. Mowery, T.L. Jones-Lepp. 2009. Contamination profiles and mass loadings of macrolide antibiotics and illicit drugs from a small urban wastewater treatment plant. *Chemosphere*. 75: 70-77.

Information is limited regarding sources, distribution, environmental behavior, and fate of prescribed and illicit drugs. Wastewater treatment plant (WWTP) effluents can be one of the sources of pharmaceutical and personal care products (PPCP) into streams, rivers and lakes. The objective of this study was to determine the contamination profiles and mass loadings of urobilin (a chemical marker of human waste), macrolide antibiotics (azithromycin, clarithromycin, roxithromycin), and two drugs of abuse (methamphetamine and ecstasy), from a small (<19 mega liters day⁻¹, equivalent to <5 million gallons per day) wastewater treatment plant in southwestern Kentucky. The concentrations of azithromycin, clarithromycin, methamphetamine and ecstasy in wastewater samples varied widely, ranging from non-detects to 300 ng L⁻¹. Among the macrolide antibiotics analyzed, azithromycin was consistently detected in influent and effluent samples. In general, influent samples contained relatively higher concentrations of the analytes than the effluents. Based on the daily flow rates and an average concentration of 17.5 ng L⁻¹ in the effluent, the estimated discharge of azithromycin was 200 mg day⁻¹ (range 63–400 mg day⁻¹). Removal efficiency of the detected analytes from this WWTP were in the following order: urobilin > methamphetamine > azithromycin with percentages of removal of 99.9%, 54.5% and 47%, respectively, indicating that the azithromycin and methamphetamine are relatively more recalcitrant than others and have potential for entering receiving waters.

Chenxi, W., A. L. Spongberg, et al. (2008). "Determination of the persistence of pharmaceuticals in biosolids using liquid-chromatography tandem mass spectrometry." *Chemosphere* 73(4): 511-8.

Sludge generated in waste water treatment process can be a major sink for some pharmaceutical and personal care products (PPCPs). The land application of sewage sludge (in the form of biosolids in the United States) can therefore potentially introduce PPCPs into the environment. After treatment, biosolids are often subjected to a storage period before land application. However, little information is available with regard to the fate of PPCPs in biosolids during the storage. In this work, the persistence of seven pharmaceuticals and one antibacterial was evaluated using ultrasonic extraction and liquid-chromatography tandem mass spectrometry (LC-MS/MS). The impacts of aeration and sunlight exposure were investigated. During the experiment, no elimination was observed for carbamazepine, triclosan, and ciprofloxacin while elimination was found for tetracycline, doxycycline, clindamycin, erythromycin, and clarithromycin. Using an availability-adjusted kinetic model, the 50% dissipation time was 37 to >77d for tetracycline, 53 to >77d for doxycycline, 1.0-1.6d for clindamycin, 1.1-1.9d for clarithromycin, and 7.0-17d for erythromycin. Those compounds were found more persistent under anaerobic conditions than aerobic condition with a longer 50% dissipation time by a factor of 1.5-2. However, minor impact was observed from sunlight irradiation.

Heidler, J. and R. U. Halden (2008). "Meta-analysis of mass balances examining chemical fate during wastewater treatment." *Environ Sci Technol* 42(17): 6324-32.

Mass balances are an instructive means for investigating the fate of chemicals during wastewater treatment. In addition to the aqueous-phase removal efficiency (ϕ), they can inform on chemical partitioning, transformation, and persistence, as well as on the chemical loading to streams and soils receiving, respectively, treated effluent and digested sewage sludge (biosolids). Release rates computed on a per-capita basis can serve to extrapolate findings to a larger scale. This review examines over a dozen mass balances conducted for various organic wastewater contaminants, including prescription drugs, estrogens, fragrances, antimicrobials, and surfactants of differing sorption potential (hydrophobicity), here expressed as the 1-octanol-water partition coefficient ($K(OW)$) and the organic carbon normalized sorption coefficient ($K(OC)$). Major challenges to mass balances are the collection of representative samples and accurate quantification of chemicals in sludge. A meta-analysis of peer-reviewed data identified sorption potential as the principal determinant governing chemical persistence in biosolids. Occurrence data for organic wastewater compounds detected in digested sludge followed a simple nonlinear model that required only $K(OW)$ or $K(OC)$ as the input and yielded a correlation coefficient of 0.9 in both instances. The model predicted persistence in biosolids for the majority (> 50%) of the input load of organic wastewater compounds featuring a $\log_{10} K(OW)$ value of greater than 5.2 ($\log_{10} K(OC) > 4.4$). In contrast, hydrophobicity had no or only limited value for estimating, respectively, ϕ and the overall persistence of a chemical during conventional wastewater treatment.

Kupper, T., L. F. de Alencastro, et al. (2008). "Concentrations and specific loads of brominated flame retardants in sewage sludge." *Chemosphere [Chemosphere]* 71(6): 1173-1180.

Many substances related to human activities end up in wastewater and accumulate in sewage sludge. The present study focuses on two classes of brominated flame retardants: polybrominated diphenyl ethers (BDE28, BDE47, BDE49, BDE66, BDE85, BDE99, BDE100, BDE119, BDE138, BDE153, BDE154, BDE183, BDE209) and hexabromocyclododecane (HBCD) detected in sewage sludge collected from a monitoring network in Switzerland. Mean concentrations ($n=16$ wastewater treatment plants) were 310, 149, 95 and 17 μg per kg dry matter for decaBDE, HBCD, penta- and octaBDE, respectively. These numbers correspond well with other studies from European countries. DecaBDE, HBCD, penta- and octaBDE showed average specific loads (load per connected inhabitant per year) in sludge of 6.1, 3.3, 2.0 and 0.3 $\text{mgcap}^{-1}\text{yr}^{-1}$, respectively. This is in line with consumption and storage of the compounds in the environment and the anthroposphere. Discrepancies observed for octaBDE and HBCD can be explained by the release from materials where these compounds are incorporated in and/or their degradation during anaerobic sludge treatment. Loads from different types of monitoring sites showed that brominated flame retardants ending up in sewage sludge originate mainly from surface runoff, industrial and domestic wastewater.

Loganathan, B., M. Phillips, et al. (2009). "Contamination profiles and mass loadings of macrolide antibiotics and illicit drugs from a small urban wastewater treatment plant." *Chemosphere* 75(1): 70-7.

Information is limited regarding sources, distribution, environmental behavior, and fate of prescribed and illicit drugs. Wastewater treatment plant (WWTP) effluents can be one of the sources of pharmaceutical and personal care products (PPCP) into streams, rivers and lakes. The objective of this study was to determine the contamination profiles and mass loadings of urobilin (a chemical marker of human waste), macrolide antibiotics (azithromycin, clarithromycin, roxithromycin), and two drugs of abuse (methamphetamine and ecstasy), from a small (<19 mega liters day⁻¹, equivalent to <5 million gallons per day) wastewater treatment plant in southwestern Kentucky. The concentrations of azithromycin, clarithromycin, methamphetamine and ecstasy in wastewater samples varied widely, ranging from non-detects to 300 ng L⁻¹. Among the macrolide antibiotics analyzed, azithromycin was consistently detected in influent and effluent samples. In general, influent samples contained relatively higher concentrations of the analytes than the effluents. Based on the daily flow rates and an average concentration of 17.5 ng L⁻¹ in the effluent, the estimated discharge of azithromycin was 200 mg day⁻¹ (range 63-400 mg day⁻¹). Removal efficiency of the detected analytes from this WWTP were in the following order: urobilin>methamphetamine>azithromycin with percentages of removal of 99.9%, 54.5% and 47%, respectively, indicating that the azithromycin and methamphetamine are relatively more recalcitrant than others and have potential for entering receiving waters.

Petreas, M. and D. Oros (2009). "Polybrominated diphenyl ethers in California wastestreams." *Chemosphere* 74(7): 996-1001.

Polybrominated diphenyl ethers (PBDEs) are used in consumer products, including electronics, fabrics, and polyurethane foam. Exposures may occur during the products' useful lifetime and also after the products' disposal. A survey of California wastestreams (e-wastes, auto shredder waste and wastewater sewage sludge) attempted to assess the relative importance of these waste streams as repositories of PBDEs. Based on measurements of PBDEs in samples of such waste streams and on assumptions regarding use patterns, e-wastes appeared to be by far the predominant waste stream with 1200 metric tons (MT) of PBDEs year⁻¹, followed by autoshredder waste (31 MT of PBDEs year⁻¹) and sewage sludge (2.3 MT of PBDEs year⁻¹). When these estimates were compared with the reported use of PBDEs in California, about half of the PBDEs could not be accounted for in the waste streams examined. This suggests that additional wastestreams, such as household wastes should be evaluated for their PBDE content. Information on the presence and fate of PBDEs in all waste streams needs to be included in decision making practices for waste management to avoid public health and ecologic catastrophes.

Radjenovic, J., M. Petrovic, et al. (2009). "Fate and distribution of pharmaceuticals in wastewater and sewage sludge of the conventional activated sludge (CAS) and advanced membrane bioreactor (MBR) treatment." *Water Research* 43(3): 831-841.

In this paper we report on the performances of full-scale conventional activated sludge (CAS) treatment and two pilot-scale membrane bioreactors (MBRs) in eliminating various pharmaceutically active compounds (PhACs) belonging to different therapeutic groups and with diverse physico-chemical properties. Both aqueous and solid phases were analysed for the presence of 31 pharmaceuticals included in the analytical method. The most ubiquitous contaminants in the sewage water were analgesics and anti-inflammatory drugs ibuprofen (14.6-31.3 $\mu\text{g/L}$) and acetaminophen (7.1-11.4 $\mu\text{g/L}$), antibiotic ofloxacin (0.89-31.7 $\mu\text{g/L}$), lipid regulators gemfibrozil (2.0-5.9 $\mu\text{g/L}$) and bezafibrate (1.9-29.8 $\mu\text{g/L}$), beta-blocker atenolol (0.84-2.8 $\mu\text{g/L}$), hypoglycaemic agent glibenclamide (0.12-15.9 $\mu\text{g/L}$) and a diuretic hydrochlorothiazide (2.3-4.8 $\mu\text{g/L}$). Also, several pharmaceuticals such as ibuprofen, ketoprofen, diclofenac, ofloxacin and azithromycin were detected in sewage sludge at concentrations up to 741.1, 336.3, 380.7, 454.7 and 299.6 ng/g dry weight. Two pilot-scale MBRs exhibited enhanced elimination of several pharmaceutical residues poorly removed by the CAS treatment (e.g., mefenamic acid, indomethacin, diclofenac, propyphenazone, pravastatin, gemfibrozil), whereas in some cases more stable operation of one of the MBR reactors at prolonged SRT proved to be detrimental for the elimination of some compounds (e.g., beta-blockers, ranitidine, famotidine, erythromycin). Moreover, the anti-epileptic drug carbamazepine and diuretic hydrochlorothiazide by-passed all three treatments investigated. Furthermore, sorption to sewage sludge in the MBRs as well as in the entire treatment line of a full-scale WWTP is discussed for the encountered analytes. Among the pharmaceuticals encountered in sewage sludge, sorption to sludge could be a relevant removal pathway only for several compounds (i.e., mefenamic acid, propranolol, and loratidine). Especially in the case of loratidine the experimentally determined sorption coefficients (K_{ds}) were in the range 2214-3321 L/kg (mean). The results obtained for the solid phase indicated that MBR wastewater treatment yielding higher biodegradation rate could reduce the load of pollutants in the sludge. Also, the overall output load in the aqueous and solid phase of the investigated WWTP was calculated, indicating that none of the residual pharmaceuticals initially detected in the sewage sludge were degraded during the anaerobic digestion. Out of the 26 pharmaceutical residues passing through the WWTP, 20 were ultimately detected in the treated sludge that is further applied on farmland. (C) 2008 Elsevier Ltd. All rights reserved.

Sidhu, J. P. S. and S. G. Toze (2009). "Human pathogens and their indicators in biosolids: A literature review." *Environment International* 35(1): 187-201.

A growing beneficial reuse of biosolids in agriculture has led to concerns about potential contamination of water resources and the food chain. In order to comprehend the potential risks of transmission of diseases to the human population, an advanced quantitative risk assessment is essential. This requires good quantitative data which is currently limited due to the methodological limitations. Consequently, further development and standardization of methodologies for the detection, enumeration and viability assessment of pathogens in biosolids is required. There is a paucity of information on the numbers and survival of enteric virus and protozoan pathogens of concern in biosolids. There is a growing urgency for the identification of more reliable alternative indicators, both index and model microorganisms, which could be used for potential public health risk assessment. In this review, we have summarized reported literature on the numbers and fate of enteric pathogens and indicators in biosolids. The advantages and limitations of the use of conventional and alternative index and model microorganisms for the prediction of pathogen presence in biosolids are also discussed. Crown Copyright (C) 2008 Published by Elsevier Ltd. All rights reserved.

Spongberg, A. L. and J. D. Witter (2008). "Pharmaceutical compounds in the wastewater process stream in Northwest Ohio." *Sci Total Environ* 397(1-3): 148-57.

In order to add to the current state of knowledge regarding occurrence and fate of Pharmaceutical and Personal Care Products (PPCP's) in the environment, influent, effluent and biosolids from three wastewater treatment facilities in Northwest Ohio, USA, and a stream containing effluent discharge from a rural treatment facility were analyzed. The three WWTP facilities vary in size and in community served, but are all Class B facilities. One facility was sampled multiple times in order to assess temporal variability. Twenty compounds including several classes of antibiotics, acidic pharmaceuticals, and prescribed medications were analyzed using ultrasonication extraction, SPE cleanup and liquid chromatography-electrospray ionization tandem mass spectrometry. The highest number of compounds and the greatest concentrations were found in the influent from the largest and most industrial WWTP facility. Short-term temporal variability was minimal at this facility. Many compounds, such as clarithromycin, salicylic acid and gemfibrozil were found at concentrations more than one order of magnitude higher than found in the effluent samples. Effluent waters contained elevated levels of carbamazepine, clindamycin and sulfamethoxazole. Differences in composition and concentration of effluent waters between facilities existed. Biosolid samples from two different facilities were very similar in PPCP composition, although concentrations varied. Ciprofloxacin was found in biosolids at concentrations (up to 46 µg/kg dry mass) lower than values reported elsewhere. Diclofenac survived the WWTP process and was found to persist in stream water incorporating effluent discharge. The low variability within one plant, as compared to the variability found among different wastewater treatment plants locally and in the literature is likely due to differences in population, PPCP usage, plant operations and/or local environment. These data are presented here for comparison with this emerging set of environmental compounds of concern.

Viau, E. and J. Peccia (2009). "Survey of wastewater indicators and human pathogen genomes in biosolids produced by class A and class B stabilization treatments." *Appl Environ Microbiol* 75(1): 164-74.

Accurate modeling of the infectious aerosol risk associated with the land application of biosolids requires an in-depth knowledge of the magnitudes and changes in pathogen concentrations for a variety of class A and class B stabilization methods. The following survey used quantitative PCR (qPCR) and culture assays to detect environmentally resistant bacterial and viral pathogens and biosolid indicator organisms for 36 biosolid grab samples. Biosolids were collected from 14 U.S. states and included 16 class B mesophilic anaerobic digestion (MAD) samples and 20 class A biosolid samples from temperature-phased anaerobic digestion (TPAD), MAD plus composting (COM), and MAD plus heat pelletization processes. The indicator concentrations of fecal coliforms and male-specific coliphages as well as pathogen genome concentrations for human adenovirus species, *Legionella pneumophila*, *Staphylococcus aureus*, and *Clostridium difficile* were significantly lower in the class A samples, and a multivariate analysis of variance ranked the stabilization processes from the lowest pathogen/indicator load to the highest as (i) class A COM, (ii) class A TPAD, and (iii) class B MAD. Human adenovirus genomes were found in 88% of the class B samples and 70 to 100% of the class A samples. *L. pneumophila*, *S. aureus*, and *C. difficile* genomes were detected at the qPCR assay detection limits in 19 to 50% of the class B and class A anaerobic digestion samples, while *L. pneumophila* was detected in 50% of the class A compost samples. When considering all the stabilization methods, both the fecal coliform and the male-specific coliphage concentrations show a significant linear correlation with the pathogen genome concentrations. This survey provides the necessary pathogen concentrations to add to biosolids aerosol risk and pathogen exposure analyses and clarifies the effectiveness of class A stabilization methods with the pathogen and indicator loads in biosolids.