

What's the Risk?

Putting the risk of biosolids into perspective



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Presentation Outline

- Project objectives and overview
- Risk assessment process
- Results
- What's next
- Q&A

After 40+ years of research, we are still being asked the same question: “Are Biosolids Safe?”

food for thought

Whole Foods Bans Produce Grown With Sludge. But Who Wins?

by ELIZA BARCLAY

January 21, 2014 3:52 PM ET



A woman shops in the produce section at Whole Foods in New York City. The company recently announced it would prohibit produce farmed using biosolids in its stores.

There's been a little bit of research...

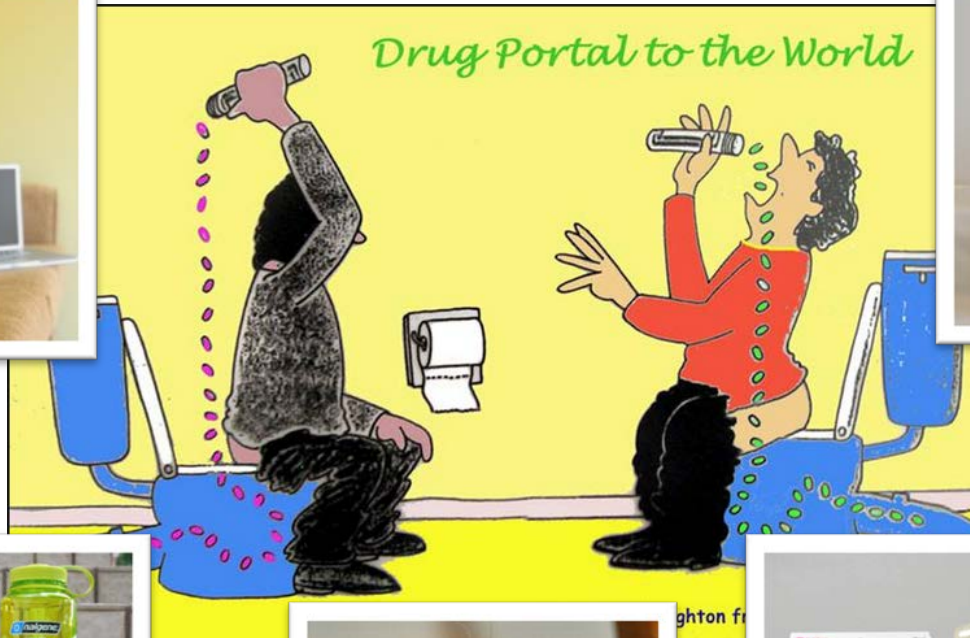
Universities involved in biosolids research

- Univ. of Maine
- Univ. of New Hampshire
- Univ. of Massachusetts
- Cornell Univ., New York*
- Penn State Univ.*
- Univ. of Delaware
- Virginia Tech*
- North Carolina State Univ.*
- Univ. of Georgia
- Univ. of Florida*
- The Ohio State Univ.*
- Univ. of MN* / USDA
- Tulane Univ.
- Univ. of Guelph / OMAFRA*
- Ryerson Univ. / OMAFRA
- Univ. of Nebraska*
- Univ. of Manitoba*
- Univ. of Alberta*
- Colorado State Univ.*
- Utah State Univ.*
- Univ. of Arizona*
- Univ. of California – Riverside*
- Washington State Univ.*
- Univ. of Washington*
- Univ. of British Columbia*
- ...and more...

* = multiple papers

Source: NBP, 2013

The issue: Trace Organics in Biosolids



Project Objectives

- Perform a human health risk assessment for trace organic chemicals in biosolids
- Provide context to help communicate risk

Benefits of the project

- Provides assurance that biosolids are safe
- Provides another resource for biosolids practitioners

Risk Assessment

What is a Risk Assessment?

$$\text{Risk} = \text{Toxicity} \times \text{Exposure}$$

- Toxicity – degree to which a substance can damage an organism
- Exposure – duration and manner in which the organism is in contact with the substance
- Risk – function of toxicity and exposure

Risk Assessment

- Risk analysis scenarios employ very conservative assumptions.
- Results are very protective of the example populations assessed in these studies.

Methodology

This study followed established U.S. EPA risk assessment methodology, which is a 4-part process:

- Select compound
- Assess exposure & toxicity
- Evaluate data
- Characterize risk

Select Compounds

- Literature Review
- Criteria for selecting organic compounds were based on:
 - Occurrence in Biosolids
 - Toxicological Relevance
 - Recognizable by the public
- 12 compounds selected

Selected Organic Compounds

Compound	Common Example or Usage
Acetaminophen	Over-the-counter pain relief, e.g. Tylenol
Ibuprofen	Anti-inflammatory, e.g. Advil
17-a ethinylestradiol - EE2	Synthetic Hormone - birth control
Fluoxetine	Anti-depressant
Azithromycin	Antibiotic e.g. Z-pack (travel meds)
Ciprofloxacin	Antibiotic E.g. Cipro (travel meds)
Erythromycin - H2O	Antibiotic - Acne medication
Ofloxacin	Antibiotic - Ear infection
Sulfamethoxazole	Antibiotic - UTIs & Bronchitis
Triclosan	Antimicrobial - Ingredient in deodorant, toothpaste, hand soap,
Bisphenol A	Plasticizer (Nalgene bottles, can liners, receipt coating)

Compound Sources

Representative concentrations
from literature review:

- Class B biosolids
- Biosolids compost
- Runoff water from land application sites

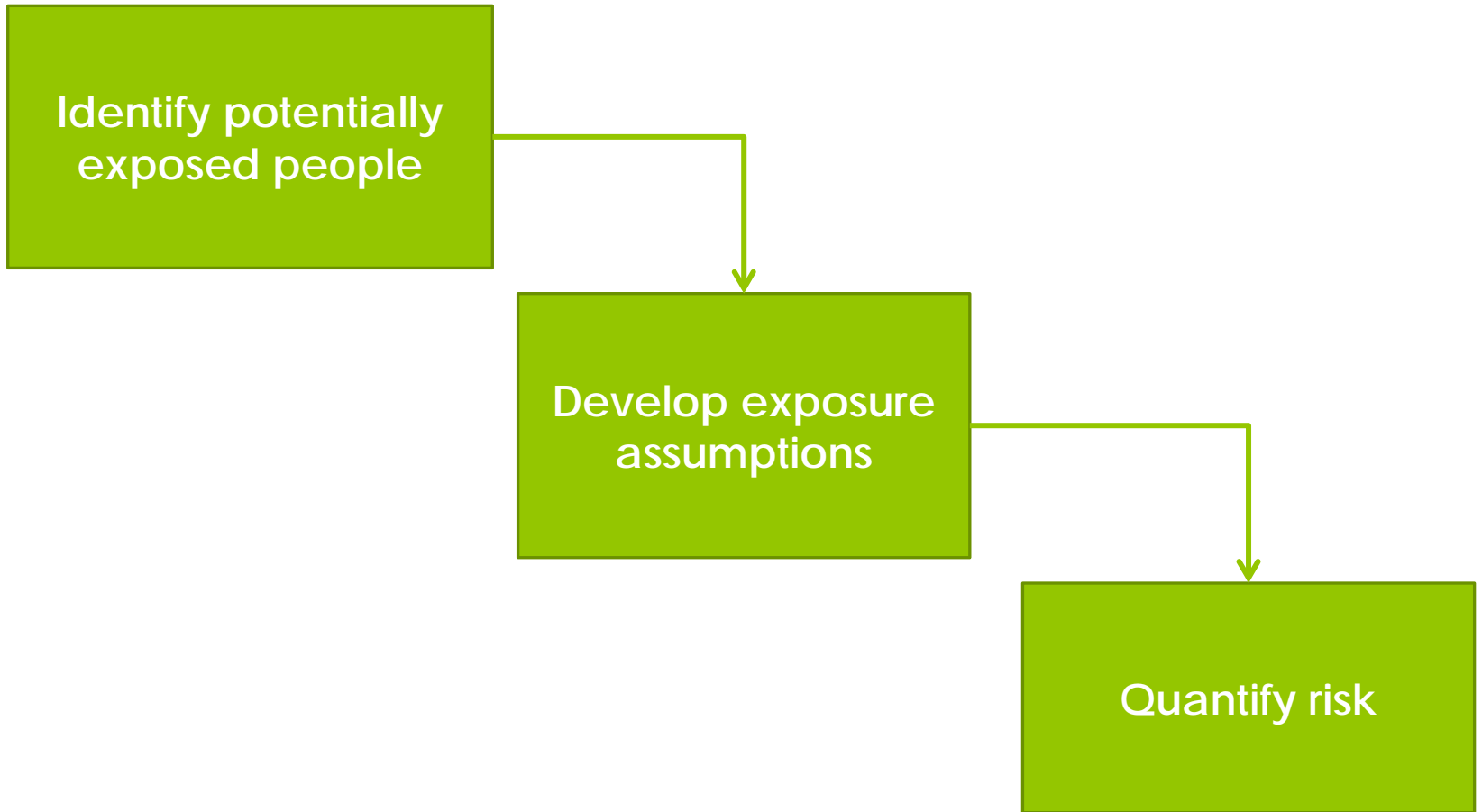


Risk Assessment

Identify potentially
exposed people

Develop exposure
assumptions

Quantify risk



Risk Assessment Scenarios

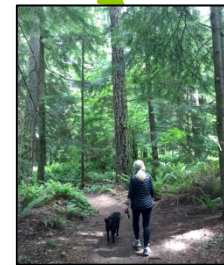
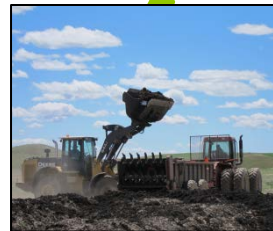


Risk Assessment Focus

- Two biosolids products:
 - Class B biosolids
 - Class A biosolids compost
- Exposed Individuals
 - Home Gardener
 - Child at Play
 - Worker
 - Forest Hiker



Exposure Scenarios



- Exposure to organic compounds through:
 - Skin contact
 - Incidental ingestion

Compost Exposure Scenarios

Adult Gardener

- Gardens with compost once a week for 20 years
- Fresh compost – no degradation
- Compost on head, hands, forearms, lower legs, feet
- Ingests 100 mg of compost each time



Compost Exposure Scenarios



Child at Play

- Plays in garden weekly for 6 years
- Fresh compost – no degradation
- Compost on head, hands, forearms, lower legs, feet
- Ingests 200 mg of compost each time

Class B Exposure Scenarios

Biosolids Applier

- Applies biosolids 220 days/year, 8 hours/day
- 25 years
- Biosolids on hands & arms
- Ingests 100 mg each day



Class B Exposure Scenarios

Adult Hiker



- Hikes monthly in forest plantations for 20 years
- Freshly applied biosolids
- Biosolids on hands and arms
- Ingests 100 mg biosolids each time
- Drinks 1 L of runoff water

Results

Risk Assessment Terminology

- ***Acceptable concentrations*** in biosolids
 - Amount that should not result in adverse health effects
 - Compare to representative concentrations in biosolids
 - Calculated for each exposure scenario

Risk Assessment Results

Representative (measured)
concentrations in biosolids

are
less
than

Acceptable
concentrations in
biosolids

Highly unlikely to result in adverse health effects

Representative vs. Acceptable Concentrations – Compost

Compound	Representative Concentration mg/kg	Acceptable Concentration mg/kg	
		Adult Gardener	Child Resident
Acetaminophen	0.0015	10,693	1,124
Fluoxetine	0.036	165	17
17-a ethinylestradiol	0.0011	0.2	0.02
Bisphenol A	9.0	197,413	20,742
Ibuprofen	0.35	1,645	173
Deca-BDE	0.24	17,646	6,374
Azithromycin	0.035	4,113	432
Ciprofloxacin	0.93	1,645	173
Erythromycin - H2O	0.0060	4,113	432
Ofloxacin	0.66	3,290	346
Sulfamethoxazole	0.001	6,580	691
Triclosan	1.2	296,120	31,114

Representative vs. Acceptable Concentrations – Biosolids

Compound	Representative Concentration mg/kg	Acceptable Concentration mg/kg	
		Adult Hiker	Worker
Acetaminophen	0.29	62,847	3,392
Fluoxetine	0.087	967	52
17-a ethinylestradiol	0.0011	1.0	0.05
Bisphenol A	9.0	1,160,255	62,617
Ibuprofen	0.35	9,669	522
Deca-BDE	1.7	113,913	4,899
Azithromycin	0.46	24,172	1,305
Ciprofloxacin	3.4	9,669	522
Erythromycin - H2O	0.020	24,172	1,305
Ofloxacin	1.8	19,338	1,044
Sulfamethoxazole	0.0056	38,675	2,087
Triclosan	17	1,740,383	93,925

Risk Communication

How else can we communicate results of the risk assessment?

Years of exposure without adverse health effects

Years of exposure to receive:

- equivalent therapeutic dose (pharmaceuticals)
- typical daily intake (other compounds)

Results – 17 α Ethinylestradiol

Exposure Scenario	Years of exposure without adverse health effects	Years of exposure to receive equivalent therapeutic dose
Child playing	98	718
Adult gardener	3,119	1,282
Adult hiker	18,239	7,533
Worker	1,237	407

Results – Acetaminophen

Exposure Scenario	Years of exposure without adverse health effects	Years of exposure to receive equivalent therapeutic dose
Child playing	4,494,188	50,514,235
Adult gardener	142,576,343	90,143,104
Adult hiker	4,334,286	2,740,328
Worker	292,391	147,890

Results – Sulfamethoxazole

Exposure Scenario	Years of exposure without adverse health effects	Years of exposure to receive equivalent therapeutic dose
Child playing	4,148,482	30,308,541
Adult gardener	131,608,932	54,085,862
Adult hiker	137,340,798	56,441,424
Worker	9,265,012	3,046,031

Results – Triclosan

Exposure Scenario	Years of exposure without adverse health effects	Years of exposure to receive equivalent therapeutic dose
Child playing	155,568	5,478
Adult gardener	4,935,335	9,775
Adult hiker	2,023,701	4,008
Occupational	136,519	216

Years of Exposure to Biosolids Compost without Adverse Effects

Compound	Adult Gardener	Child at Play
Acetaminophen	142,576,343	4,494,188
Fluoxetine	91,395	2,881
17-a ethinylestradiol (EE2)	3,119	98
Bisphenol A	436,635	13,763
Ibuprofen	94,006	2,963
Deca-BDE	1,470,486	159,343
Azithromycin	2,350,159	74,080
Ciprofloxacin	35,379	1,115
Erythromycin - H2O	13,709,264	432,133
Ofloxacin	99,704	3,143
Sulfamethoxazole	131,608,932	4,148,482
Triclosan	4,935,335	155,568

Years of Exposure to Receive Equivalent Dose – Class A Compost

Compound	Adult Gardener	Child at Play
Acetaminophen	90,143,104	50,145,235
Fluoxetine	75,119	42,095
17-a ethinylestradiol (EE2)	1,282	718
Bisphenol A*	1	0.1
Ibuprofen	77,266	2,963
Deca-BDE*	0.07	0.04
Azithromycin	965,819	541,224
Ciprofloxacin	36,348	20,369
Erythromycin - H2O	22,535,776	12,628,559
Ofloxacin	81,948	45,922
Sulfamethoxazole	54,085,862	30,308,541
Triclosan	9,775	5,478

Years of Exposure to Class B Biosolids without Adverse Effects

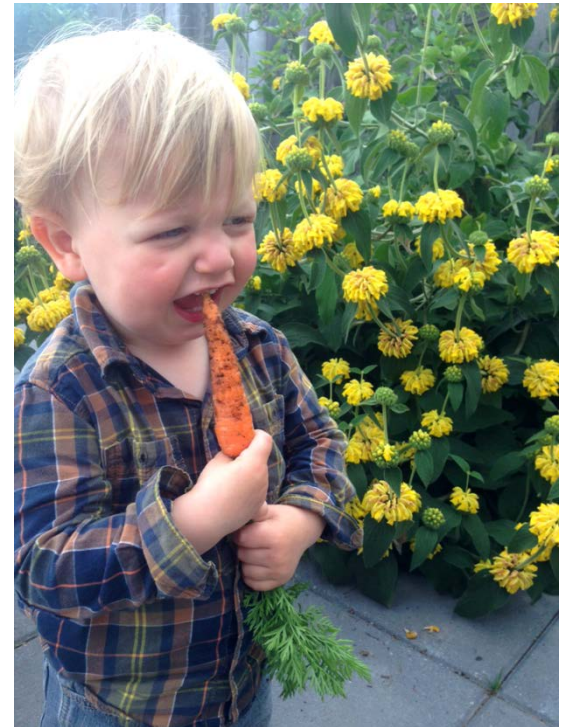
Compound	Adult Hiker	Worker
Acetaminophen	4,334,286	292,391
Fluoxetine	222,271	14,994
17-a ethinylestradiol (EE2)	18,329	1,237
Bisphenol A	2,566,226	173,118
Ibuprofen	552,502	37,272
Deca-BDE	1,340,151	25,728
Azithromycin	1,050,956	70,897
Ciprofloxacin	57,638	3,888
Erythromycin - H2O	24,171,981	1,630,642
Ofloxacin	217,032	14,641
Sulfamethoxazole	137,340,798	9,265,012
Triclosan	2,023,701	136,519

Years of Exposure to Receive Equivalent Dose – Class B Biosolids

Compound	Adult Hiker	Occupational
Acetaminophen	2,740,328	147,890
Fluoxetine	182,689	9,859
17-a ethinylestradiol (EE2)	7,533	407
Bisphenol A*	1	4
Ibuprofen	454,112	24,507
Deca-BDE*	0.03	0.001
Azithromycin	431,900	23,309
Ciprofloxacin	59,217	3,196
Erythromycin - H2O	39,734,763	2,144,406
Ofloxacin	178,383	9,627
Sulfamethoxazole	56,441,424	3,046,031
Triclosan	4,008	216

Conclusion

- Biosolids are highly unlikely to pose a health risk to humans from direct contact routes of exposure.



Next Steps

- Create information materials
 - Key message points
 - Simple handouts
 - Web content
- Prepare Research Note for NW Biosolids
- Support other municipalities in further developing this approach
- Voluntary survey of organic compounds in biosolids



Questions?

Pesticides



Pesticide name	Estimated amount in a single serving of apple	Estimated amount in compost	Years to equivalent exposure (adult gardener)
Thiabendazole	0.07 mg	.06 mg	175
Endosulfan II	0.007 mg	0.001 mg	796
Diazinon	0.02 mg	0.008 mg	383

Risk Assessment Terminology

- Determined ***Acceptable Daily Intake*** (ADI) for each scenario

ADI = the amount of a chemical that someone may be exposed to daily over an extended period of time **without** experiencing harmful effects.

Results – Azithromycin

Exposure Scenario	Years of exposure without adverse health effects	Years of exposure to receive equivalent therapeutic dose
Child playing	74,080	541,224
Adult gardener	2,350,159	965,819
Adult hiker	1,050,956	431,490
Worker	70,897	23,309

Results - Triclosan

Exposure Scenario	Representative Concentration compost / biosolids (mg/kg)	Acceptable Concentration Triclosan (mg/kg)
Child playing	1.2	31,114
Adult gardener	1.2	296,120
Adult hiker	17	1,740,383
Worker	17	93,925

Results – 17 α Ethinylestradiol

Exposure Scenario	Representative Concentration compost / biosolids (mg/kg)	Acceptable Concentration EE2 (mg/kg)
Child playing	0.0011	0.02
Adult gardener	0.0011	0.2
Adult hiker	0.0011	1.0
Worker	0.0011	0.05

CAS	Chemical of Potential Concern	Therapeutic Dose (mg)	Description	Source
Analgesic				
103-90-2	Acetaminophen	1000	2 caplets of Extra Strength Tylenol	http://
Anti-depressant				
54910-89-3	Fluoxetine	20	Recommended starting daily dose of Prozac	http://
Birth control				
57-63-6	17-a ethinylestradiol (EE2)	0.01	Low dose birth control (Lo Loestrin)	http:// ction=
Phthalate				
80-05-7	Bisphenol A	--	Not applicable. There are no therapeutic dos	
NSAID				
15687-27-1	Ibuprofen	200	1 tablet of Advil	http://
Flame Retardants - PBDE				
1163-19-5	Deca-BDE	--	Not applicable. There are no therapeutic dos	
Antibiotics				
83905-01-5	Azithromycin	250	Lowest daily dose	http:// ction=
85721-33-1	Ciprofloxacin	250	Lowest daily dose	http:// _02078
114-07-8	Erythromycin - H2O	1000	Recommended daily dose	http:// lbl.pdf
82419-36-1	Ofloxacin	400	Lowest daily dose	http:// 1s014!
723-46-6	Sulfamethoxazole	400	Lowest daily dose	http:// ction=
Anti-microbial				
3380-34-5	Triclosan	87	Intake from single use of soap	See ca