Toxicology and Risk Assessment Challenges with Evaluating Health Effects of PFAS

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September 13, 2019

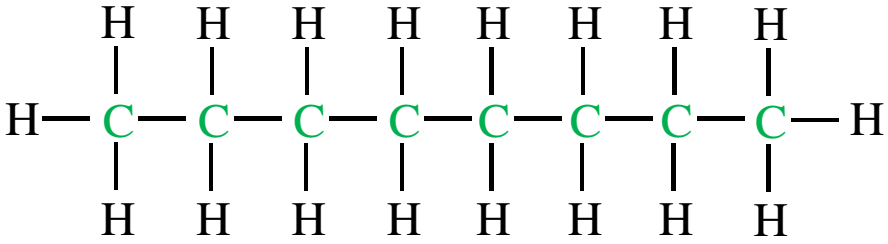
TOPICS

- Quick primer on the risk assessment process
- How toxicity values for PFOS are derived
  (…and why do they differ so much)
- How drinking water guidelines/standards are derived (…and why do they differ so much)
- Soil Screening Levels (SSLs) for the soil-to-groundwater pathway
- Current work to investigate agronomic exposure pathways for PFOS

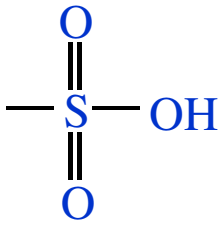
PFOS
(perfluorooctane sulfonic acid)

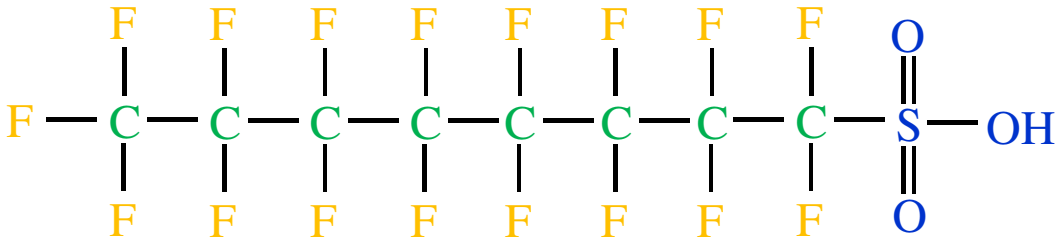
Carbon backbone

Acid Group



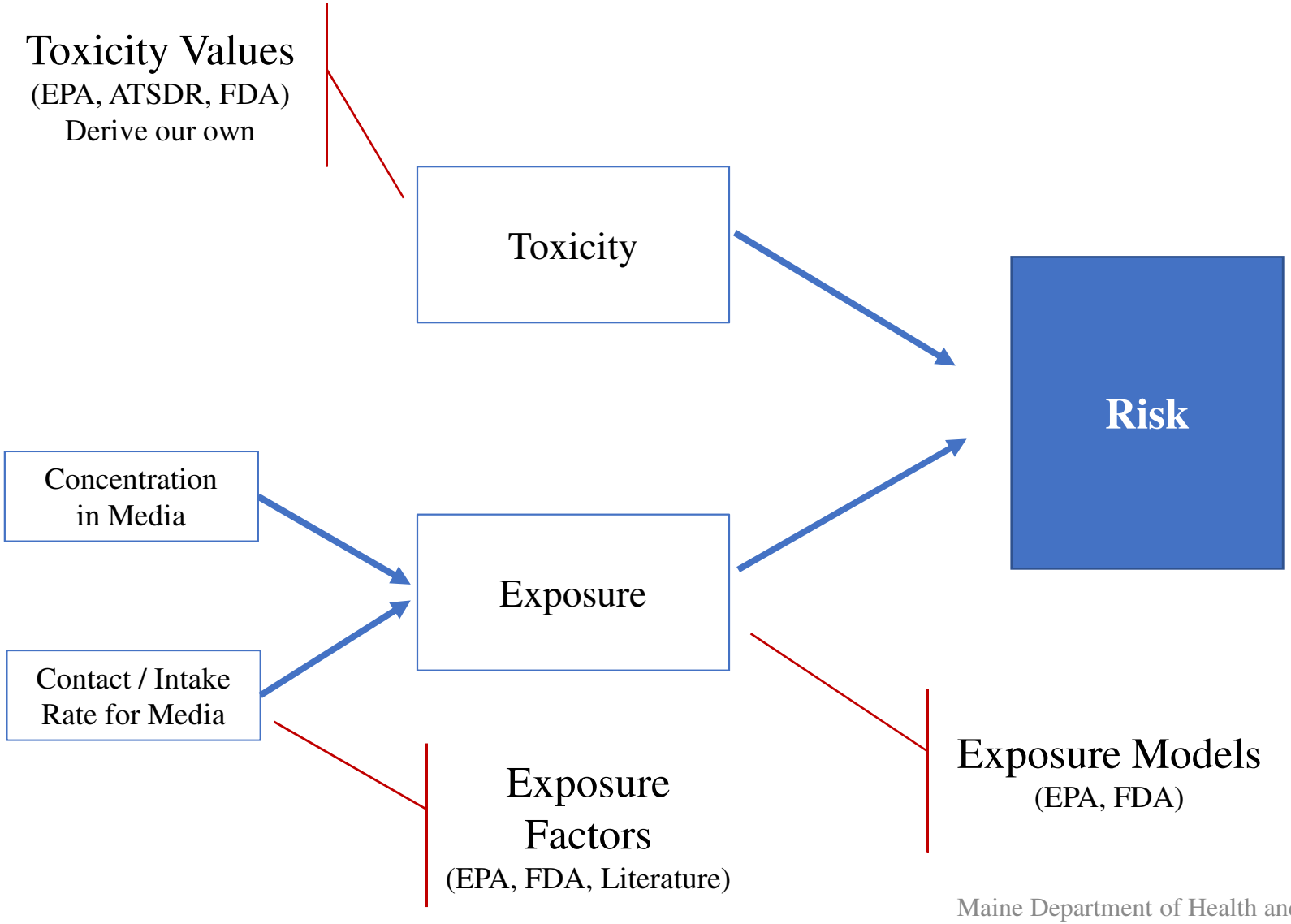
Octane



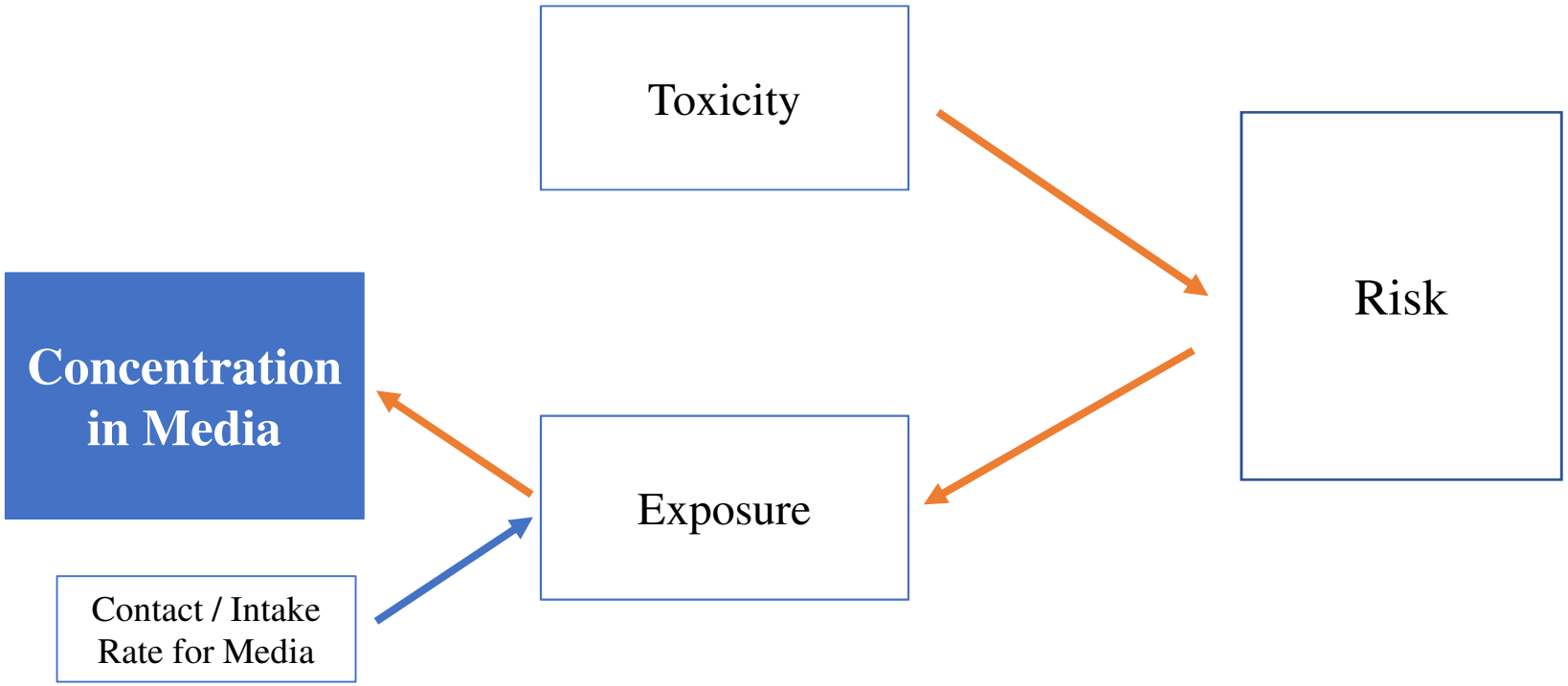


Perfluorooctane sulfonic acid (PFOS)

Risk Assessment



Risk Assessment



Available Toxicity Data for PFOS

Human Studies

Liver damage*

Thyroid hormone disruption*

Decreased antibody response to vaccines*

Lower birth weight (LBW)*

Changes in cholesterol

Hypertension during pregnancy

Bladder, colon and prostate cancer

Animal Studies

Increased liver size / liver damage*

Thyroid hormone disruption*

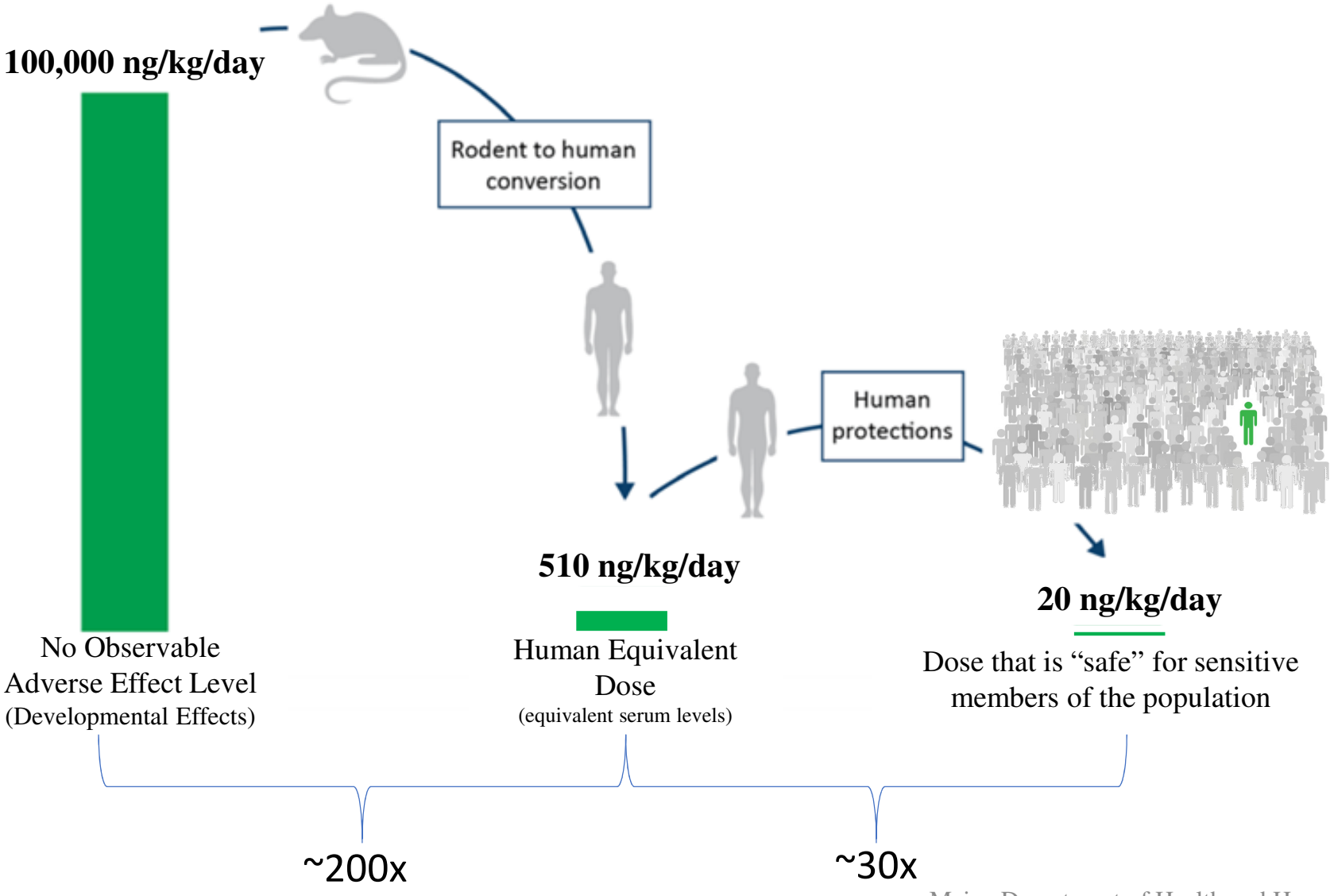
Changes in immune function*

LBW and other developmental effects*

Liver cancer

Increased kidney weight

USEPA's Derivation of a Toxicity Value for PFOS



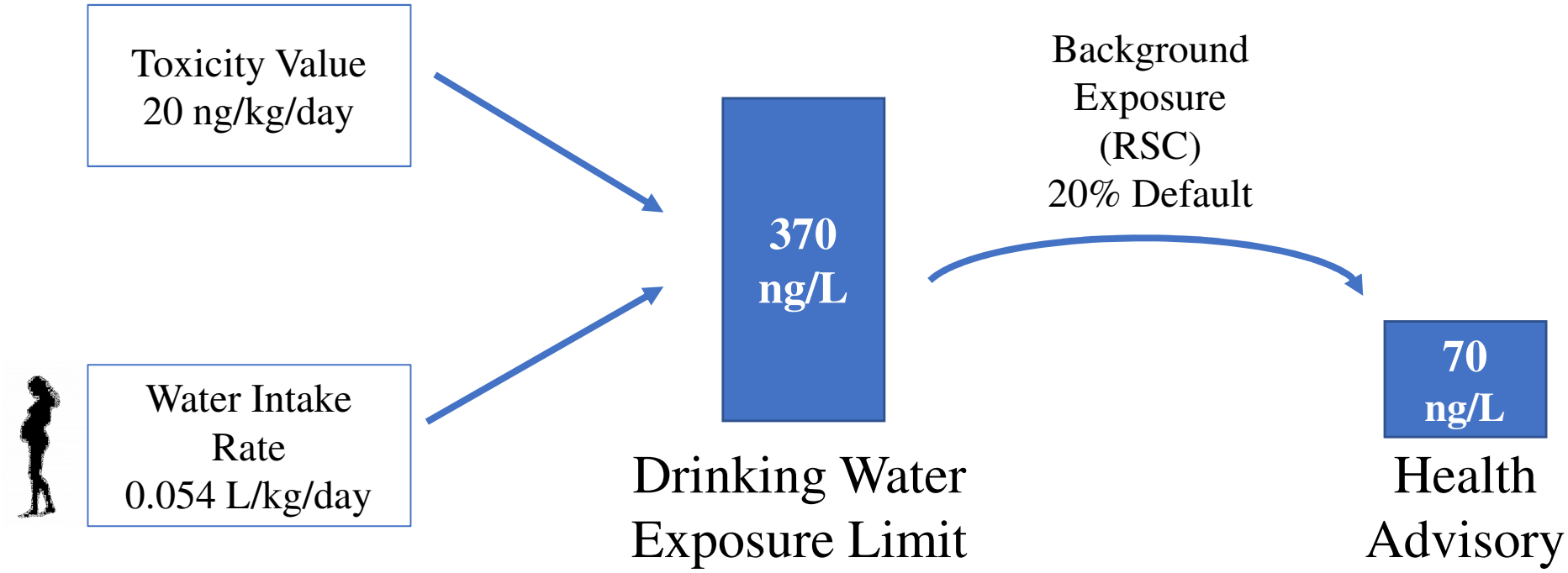
Differences in Toxicity Values for PFOS

	Agency	Endpoint	Species	Human equivalent dose (ng/kg/day)	Cumulative uncertainty factor	Reference dose (ng/kg/day)
Federal	EPA	Developmental effects	Rats	510	30	**20**
	ATSDR	Developmental effects	Rats	515	300	**2***
States	ME, VT, CT†	Developmental effects	Rats	510	30	**20**
	MA	Developmental effects	Rats	510	100	**5***
	MN	Immune effects	Mice			**3**
	NH	Immune effects	Mice			**3**
	MI	Immune effects	Mice			**3***
	NJ, NY, CA	Immune effects	Mice			**2***
International	Health Canada	Liver effects	Rats	150	25	**60**
	EFSA	Changes in cholesterol	Humans	2	1	**2**

5 % Increase in cholesterol levels

* Proposed/Draft. † ME, VT, CT all using EPA's toxicity value (FDA is also using EPA's toxicity value).

Deriving EPA's Drinking Water Health Advisory

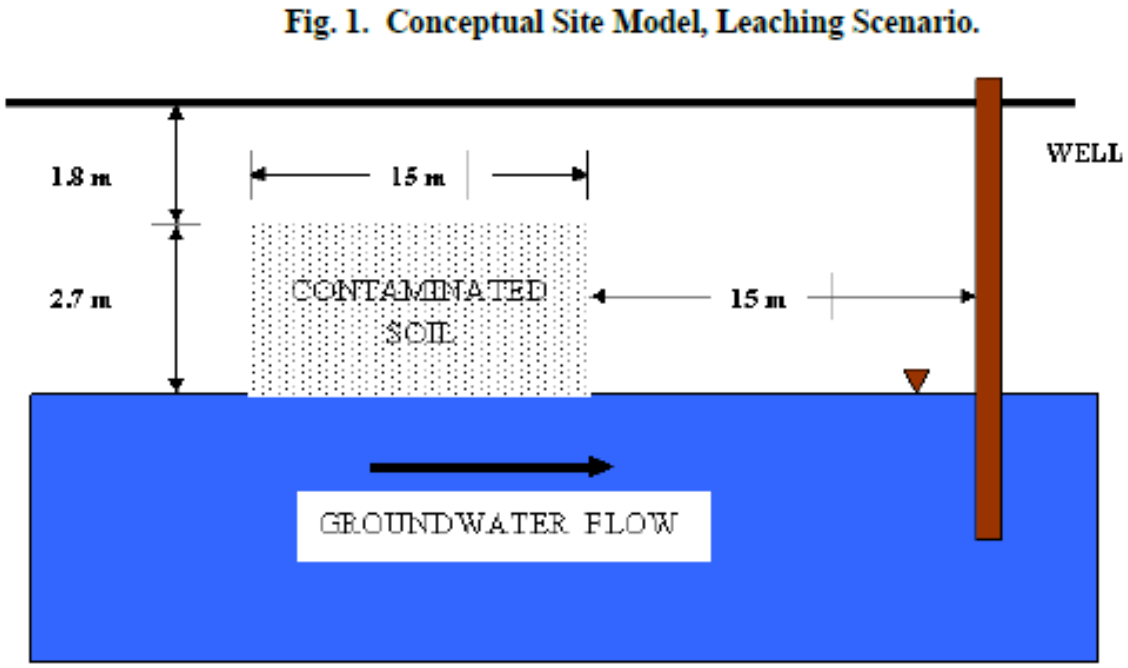


Other Drinking Water Guidelines for PFOS

	Agency	Reference dose (ng/kg/day)	Receptor	Drinking water intake (L/kg/day)	Relative source contribution (%)	Drinking water guideline (ng/L)
Federal	EPA	20	Lactating woman	0.054	20	**70**
	ATSDR	2	Infant, birth to 1 yr	0.143	No RSC	**14**
States	VT	20	Bottle-fed infant	0.175	20	**20**
	MA	5	Lactating woman	0.054	20	**20***
	MI	3	Breastfed infant	0.047	50	**16***
	MN	3	Breastfed infant	0.047	50	**15**
	NH	3	Breastfed infant	0.047	50	**15***
	NJ	2	Adult	0.029	20	**13***
	NY	2	Infant	0.151	60	**10***
International	Health Canada	60	Adult	0.021	20	**600**

* Proposed / Draft

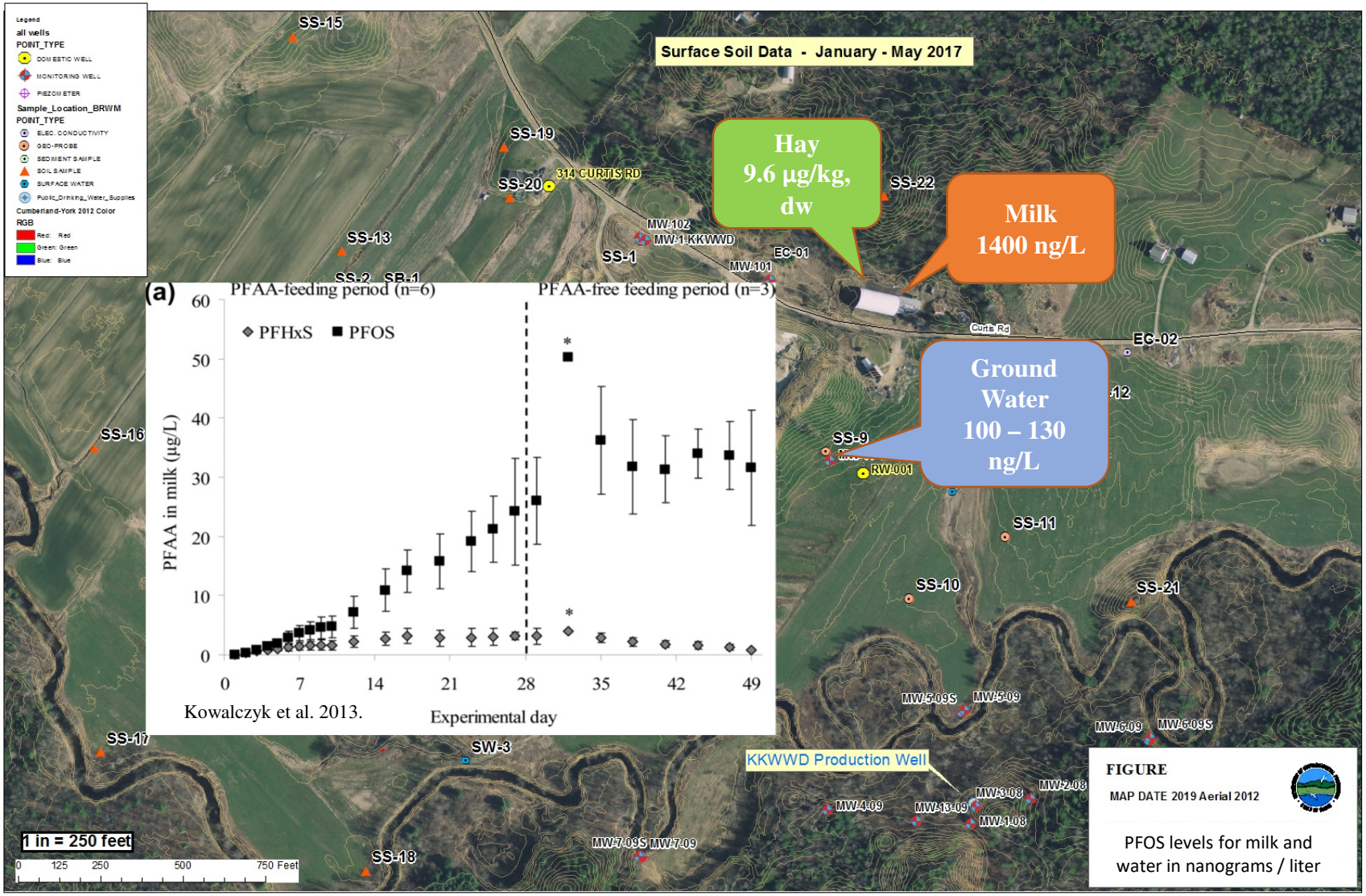
PFOS Soil SLs for Soil-to-Groundwater Exposure Pathway



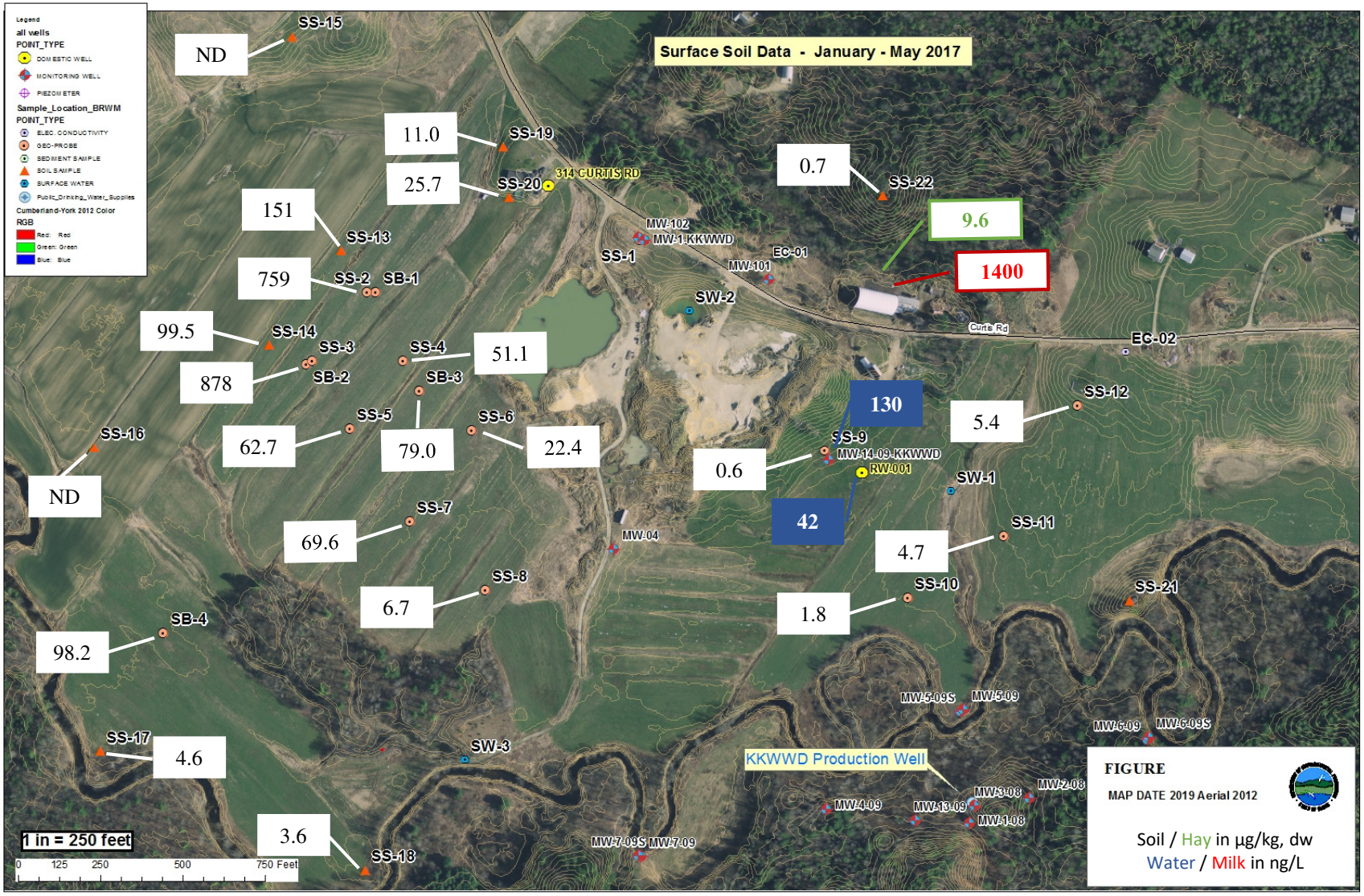
PFOS
5.2 µg/kg

Based on Chapter 418 risk standard of 0.5 HI, USEPA RSL tap water model modified with use of SESOIL soil to groundwater model, and USEPA RfD.

Stoneridge Farm



PFOS Levels for Stoneridge Farm



ST1
ST2

PFOS Soil Screening Levels for Residential Soil Exposure Pathway - 2017

PFOS

2700 µg/kg, dw

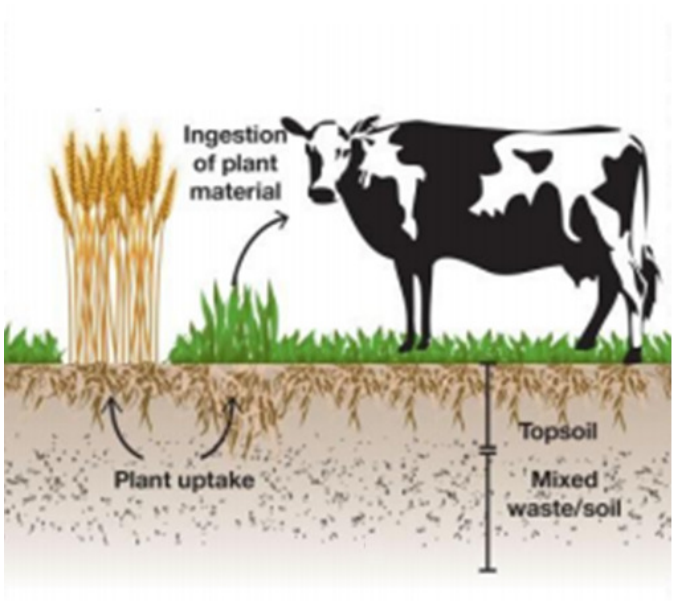
Based on USEPA RfD of 20 ng/kg/day, 95th percentile incidental soil ingestion rate for a 1-6 year old child, 150 days / year.

Slide 14

ST1 I would use the RAG here as the chapter 418 standard wouldn't necessarily be the applicable standard applied in this case, i.e., that is a new site with contaminated soils where you don’t know the source. DEP would use the soil RAG to evaluate.
Simones, Thomas, 9/11/2019

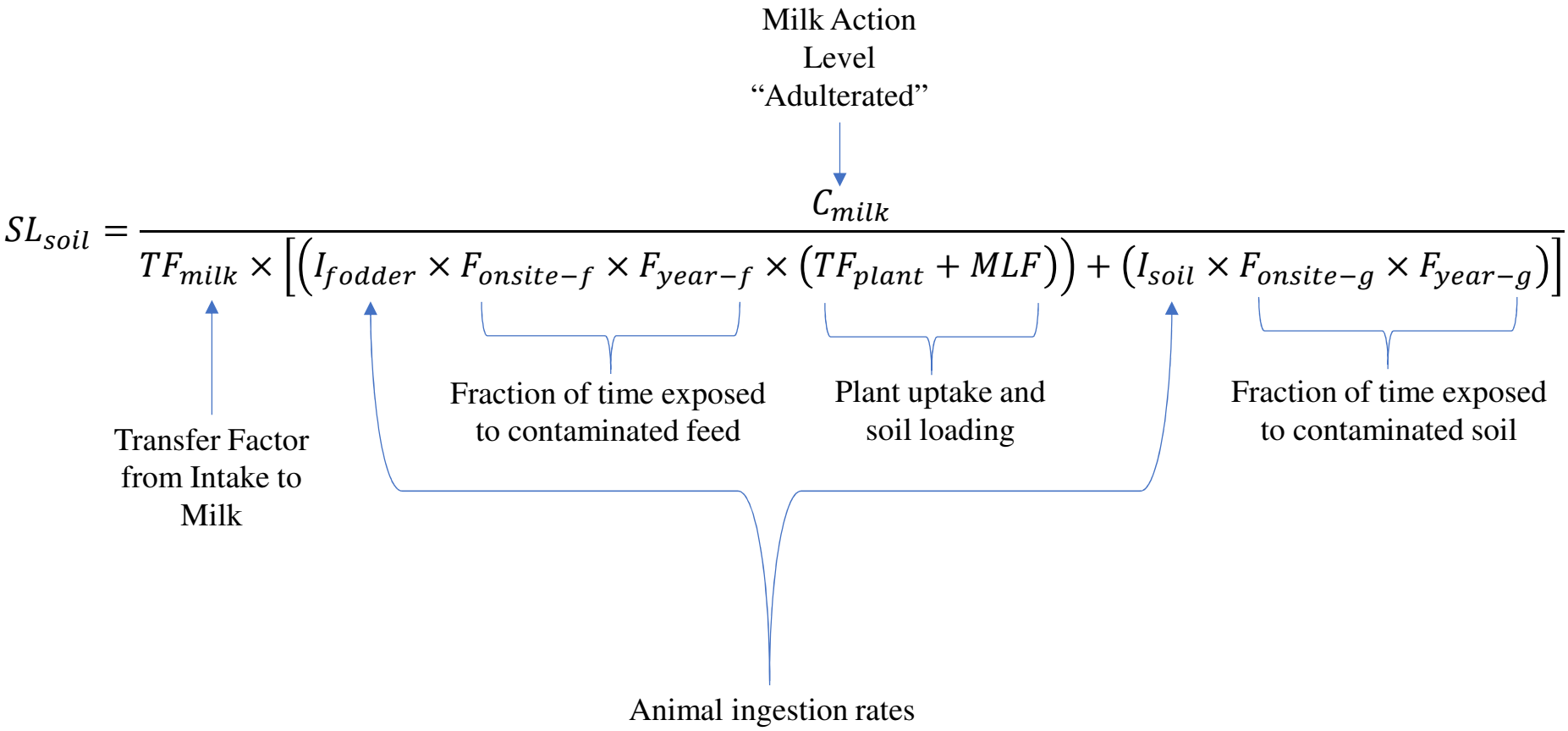
ST2 I would also use the 2018 RAG of 1700 ug/kg to avoid any confusion and mention that at the time of discovery the RAG was 2700.
Simones, Thomas, 9/11/2019

What would be a PFOS soil screening level for the dairy farming scenario?



Soil → Hay/Corn → Cow → Milk → Child

USEPA PRGR Soil Screening Level Equation Agronomic Pathway



Source:
Modified equation from U.S. EPA Preliminary Remediation Goals for Radionuclides, consumption of milk back calculated to soil - https://epa-prgs.ornl.gov/radionuclides/users_guide.html

Deriving a Milk Action Level for "adulterated" Milk

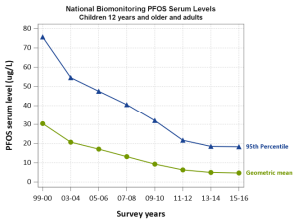
Toxicity Value
20 ng/kg/day

90th Percentile
Milk Intake
0.074 L/kg/day

1-2 year old

270 ng/L

Milk Exposure Limit



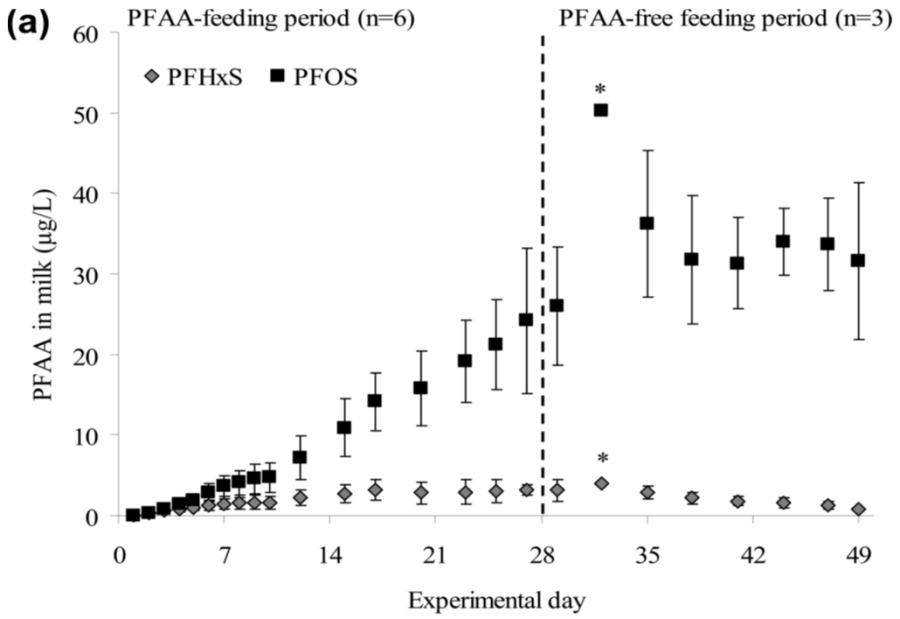
Relative Source Contribution
80%

210 ng/L

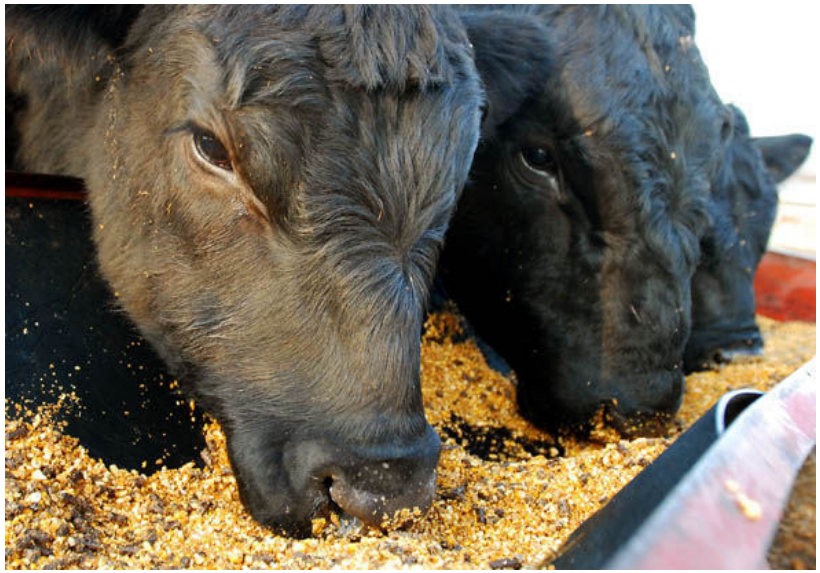
Action Level

PFOS Milk Transfer Factor (TF_{milk})

PFOS in Milk



- Calculated TF_{milk} = 0.005
- Modeled TF_{milk} = 0.02 to 0.08



Source:

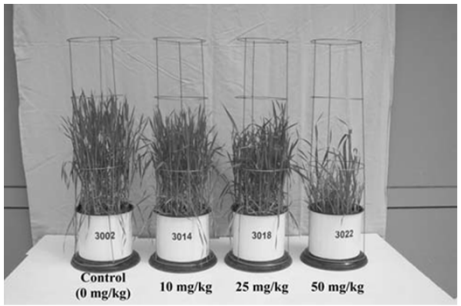
Kowalczyk et al. 2013. Absorption, distribution, and milk secretion of the perfluoroalkyl acids PFBS, PFHxS, PFOS, and PFOA by dairy cows fed naturally contaminated feed. J Agric Food Chem. 61(12):2903-12. https://doi.org/10.1021/jf304680j

Vestergren et al. 2013. Bioaccumulation of perfluoroalkyl acids in dairy cows in a naturally contaminated environment. Environ Sci Pollut Res Int. 20(11):7959-69. https://doi.org/10.1007/s11356-013-1722-x

PFOS Hay Transfer Factor (TF_{plant})

$TF_{hay} = 0.07$

$TF_{hay} = 0.1$



$TF_{hay} = 0.5$

PFOS Corn Transfer Factor (TF_{plant})

$TF_{corn} = < 0.08$

$TF_{corn} = 0.04$

$TF_{corn} = 0.16$

Plant Soil Mass Loading Factor (*MLF*)

Processes for transfer of soil to plant surface

- Rain splash
- Wind erosion
- Soil disturbance by mechanical equipment

USEPA PRGR Defaults

- Default = 0.25, range 0.001 to 0.5
- Geometric mean of 11 studies* = 0.034
  (pasture plants only)

$$MLF = 0.034$$

CORN
0.0014

Source:
*Hinton, T.G. 1992. Contamination of plants by resuspension: a review, with critique of measurement methods. Sci Total Environ. 121:117-193. DOI: https://doi.org/10.1016/0048-9697(92)90314-I
**Pinder III, J.E. et al. 1989. Mass loading of soil particles on plant surfaces. Health Physics. 57(6):935-942.

Example Soil SL Calculation for Hay

13,800 ng/kg dw
(13.8 µg/kg dw)

204 ng/kg

$$SL_{soil} = \frac{C_{milk}}{TF_{milk} \times \left[\left(I_{fodder} \times F_{onsite-f} \times F_{year-f} \times \left(TF_{plant} + MLF\right)\right) + \left(I_{soil} \times F_{onsite-g} \times F_{year-g}\right)\right]}$$

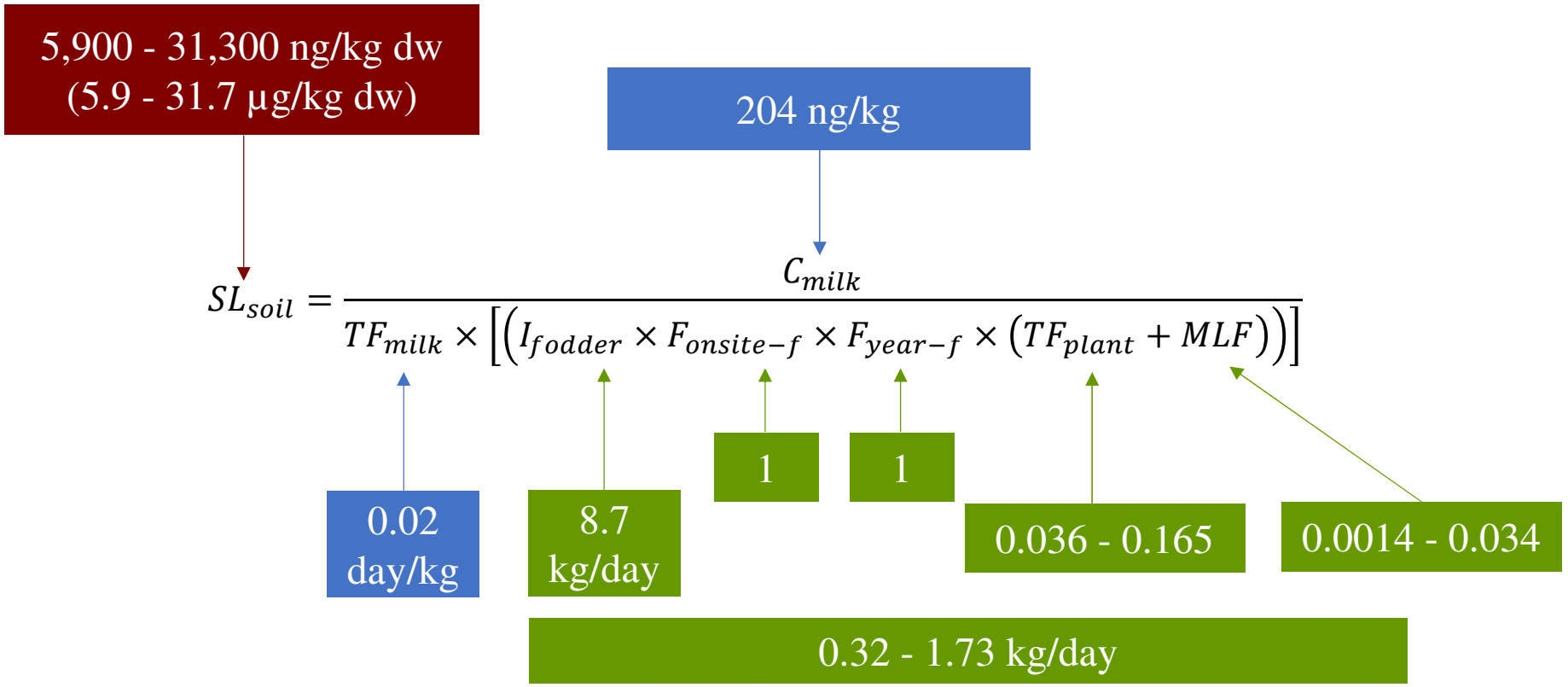
TF_{milk}	I_{fodder}	$F_{onsite-f}$	F_{year-f}	TF_{plant}	MLF	I_{soil}	$F_{onsite-g}$	F_{year-g}
0.02 day/kg	6.5 kg/day	1	1	0.07	0.034	0.13 kg/day	1	0.5

0.68 kg/day

0.065 kg/day

Source:
Modified equation from U.S. EPA Preliminary Remediation Goals for Radionuclides, consumption of milk back calculated to soil - https://epa-prgs.ornl.gov/radionuclides/users_guide.html

Example Soil SL Calculation for Corn Silage



Source:
Modified equation from U.S. EPA Preliminary Remediation Goals for Radionuclides, consumption of milk back calculated to soil - https://epa-prgs.ornl.gov/radionuclides/users_guide.html

Example Soil Screening Levels for Dairy Farm Scenarios

EPA "Subsistence Dairy Farm"

- Diet: Hay (65%) Corn (20%) Grain (15%)

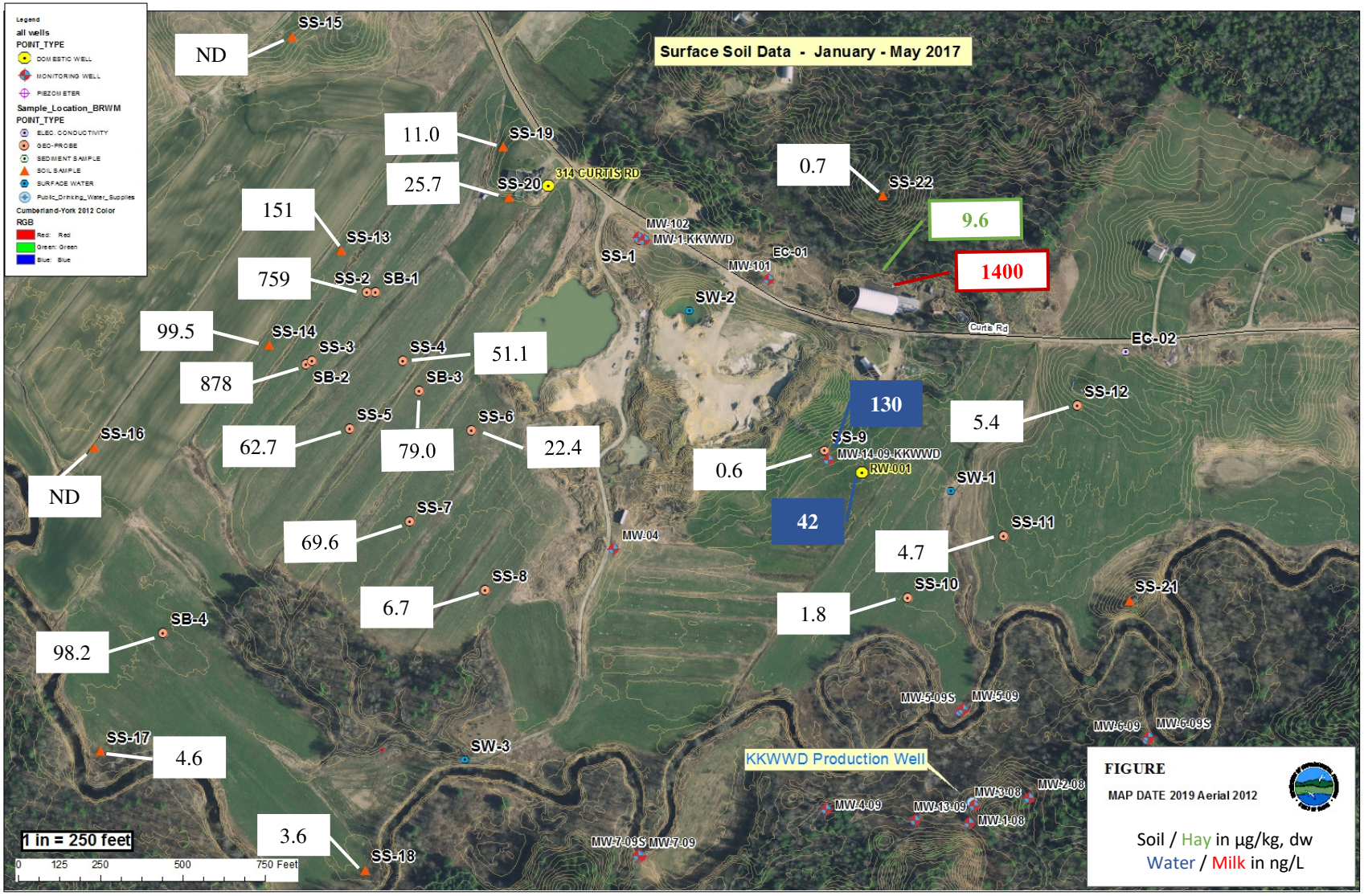
SSL = 4 – 6 µg/kg, *dw*

Average Maine Dairy Farm

- Diet: Hay (28%) Corn (37%) Grain (35%)

SSL = 4 – 10 µg/kg, *dw*

PFOS Levels for Stoneridge Farm



Model Estimated PFOS Milk Levels based on Stoneridge Farms Soil Levels

Stoneridge Farms PFOS site-wide soil level estimates (ug/kg dry weight)	Model estimated PFOS milk (ng/L)
123 (arithmetic average)	4,100
25 (geometric mean)	840

Initial average measured PFOS milk levels at Stoneridge Farms = 1,117 ng/L

Next Steps

Soil-to-Corn PFOS Uptake Study (DEP, MECDC, DACF)

- Identified biosolid amended soils with elevated PFOS levels for a plant uptake study
- Confirmed soils are being used to grow corn
- Collect matched soil and silage corn samples for PFOS analysis
- Analyze to derive a transfer factor

Review

- ATSDR, USDA, FDA, other states
- Monitoring / evaluating new literature / reports
- Looking for more farms to test model against

Two Big Questions to End With:

- Should Maine continue to rely on EPA toxicity values?

- What about other PFAS (e.g., PFOA, PFHxS, PFHxA, PFNA, etc)?

Questions?

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