

Perspectives on Microbial Water Quality, Risk Reduction, the Current Standards and Testing Requirements, and Developing a Future Framework

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Future Framework


▶ Short-term

- ▶ PSR provisions = Ag water adequate for intended purpose; with safe harbors defined in guidance that can be updated
- ▶ More discussion needed as to what would be defined in guidance as adequate (current PSR rule provisions = what?)

▶ Long-term

- ▶ Need a 3-5 year risk assessment collecting data in key produce production areas using standardized methodology looking at indicators, human pathogens (STEC & *Salmonella*) and next generation sequencing microbiome analysis to try and identify a portfolio of index organisms that correlate with risk + die off studies.
- ▶ Results to be incorporated in FDA guidance.

What's best for public health (it's not about cost or burden to farmers)

- ▶ How important is it that Ag water be safe?
 - ▶ How important is it to *test* Ag water?
 - ▶ Is Ag water already tested?
 - ▶ Is current testing approach inadequate/ unsafe?
 - ▶ What else is industry doing?
- RISK
- 

How important is Ag water to food safety?

Outbreak Data Attributed to Produce RACs Other Than Sprouts 2003-2012					
Commodity	Agent	Outbreaks	Cases	Hospitalizations	Deaths
berries	<i>Cyclospora</i>	2	67	2	0
berries	<i>Salmonella</i>	2	20	1	0
green onion	<i>Hepatitis A</i>	1	919	128	3
herb	<i>Cyclospora</i>	2	622	1	0
herb	<i>E. coli</i> O157:H7	1	108	8	0
leafy greens	<i>Cyclospora</i>	1	38	0	0
leafy greens	<i>E. coli</i> O157:H7	3	60	15	0
leafy greens	<i>Salmonella</i>	1	15	1	0
melon	<i>Listeria monocytogenes</i>	1	147	143	33
melon	<i>Salmonella</i>	8	514	140	6
melon	<i>Shigella sonnei</i>	1	56	3	0
nut*	<i>E. coli</i> O157:H7	1*	8*	3*	0*
nut	<i>Salmonella</i>	2	95	12	1
other	<i>Cyclospora</i>	2	172	0	0
other	<i>Salmonella</i>	6	1925	370	2
tomato	<i>Salmonella</i>	8	661	80	0
unknown	<i>Salmonella</i>	6	860	132	0
RAC Total		48	6287	1039	45

Became annual
138,000 illnesses
which became
>900,000 annual
illnesses, of which
the rule may
prevent 515,000

Table 8. Mean Reduction in Risk of Contamination/ Benefits by Pathway

Mean Reduction in Risk of Contamination/ Benefits by Pathway attributable to Produce RACs other than sprouts					
Contamination Pathway	Covered Dollar Burden (millions)	Likelihood of Being the Path of Contamination	Effectiveness of Controls	Reduction in Risk	Benefits (millions)
Agricultural Water (growing/harvest)	\$2,045	16.32%	54.49%	8.89%	\$182
Agricultural Water (postharvest)	\$2,045	14.37%	72.55%	10.42%	\$213
Biological Soil Amendments	\$2,045	13.81%	65.62%	0.7%*	\$15
Worker Health and Hygiene (growing/harvest)	\$2,045	15.62%	66.04%	10.32%	\$211
Worker Health and Hygiene (postharvest)	\$2,045	15.20%	73.50%	11.17%	\$228
Domesticated and Wild Animals	\$2,045	14.09%	58.04%	8.18%	\$167
Equipment, Tools, Building and Sanitation (growing/harvest)	\$2,045	4.18%	56.71%	2.37%	\$49
Equipment, Tools, Buildings and Sanitation (postharvest)	\$2,045	6.42%	67.97%	4.36%	\$89
Total				56.43%	\$1,154

Excerpted from the FDA Regulatory Impact Analysis Docket No. FDA-2011-N-0921

Why is “effectiveness of control” so low?

- ▶ Can more research improve public health benefit of ag water?
 - ▶ “Systems” approach vs testing?
 - ▶ Better indicator (s) or index organisms?
 - ▶ Better sampling plan to address inherent variability?

Is Ag water currently tested?

- ▶ USDA ERS study of prevalence of audits- unpublished = unsharable
 - ▶ Audits require water testing

What problem are we trying to solve?

RIA says 15.2% water doesn't meet "no detectable E. coli" and 2.4% don't meet 126/410 standard



Doing it right

Does the shade of green matter?

Doing it wrong

No understanding of water today

Alternatives are not an alternative

- ▶ 112.12: You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have **adequate scientific data or information** to support a conclusion that the alternative would provide the **same level of public health protection** as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions
- ▶ What is the public health protection?

What else is going on?

- ▶ CPS: >35 related projects; \$7M funding
- ▶ Science is evolving
- ▶ Climate is changing; risks may change, microbiome may change

Conversation Impediments

- ▶ E. coli is not the best indicator, but what is?
 - ▶ Is there a universal indicator or index that applies everywhere in the world regardless of water system?
 - ▶ If yes, will more research reveal this?
 - ▶ If not, how does a codified rule accommodate this?
- ▶ What is “the number”?
 - ▶ The difference between 126 and 127 cfu/ 100 ml
 - ▶ How do you avoid sampling when and where you know numbers will be low?
- ▶ What is “safe and adequate for its intended use”
 - ▶ Different crops, different water uses, role of die off, subsequent handling steps



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