Quantitative Risk Assessment (QRA) to Support the Proposed Produce Rule

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QRA - Summary

- Referenced in the proposal; not published in the Federal Register for comment
- Developed with good scientific methodology and algorithms appropriate for their use in a quantitative risk assessment
- Inputs to those calculations are largely based on assumptions, “expert opinion”, and data taken from published studies with unclear context
- Establishes a protocol that commodities and practices can use to demonstrate “low risk”

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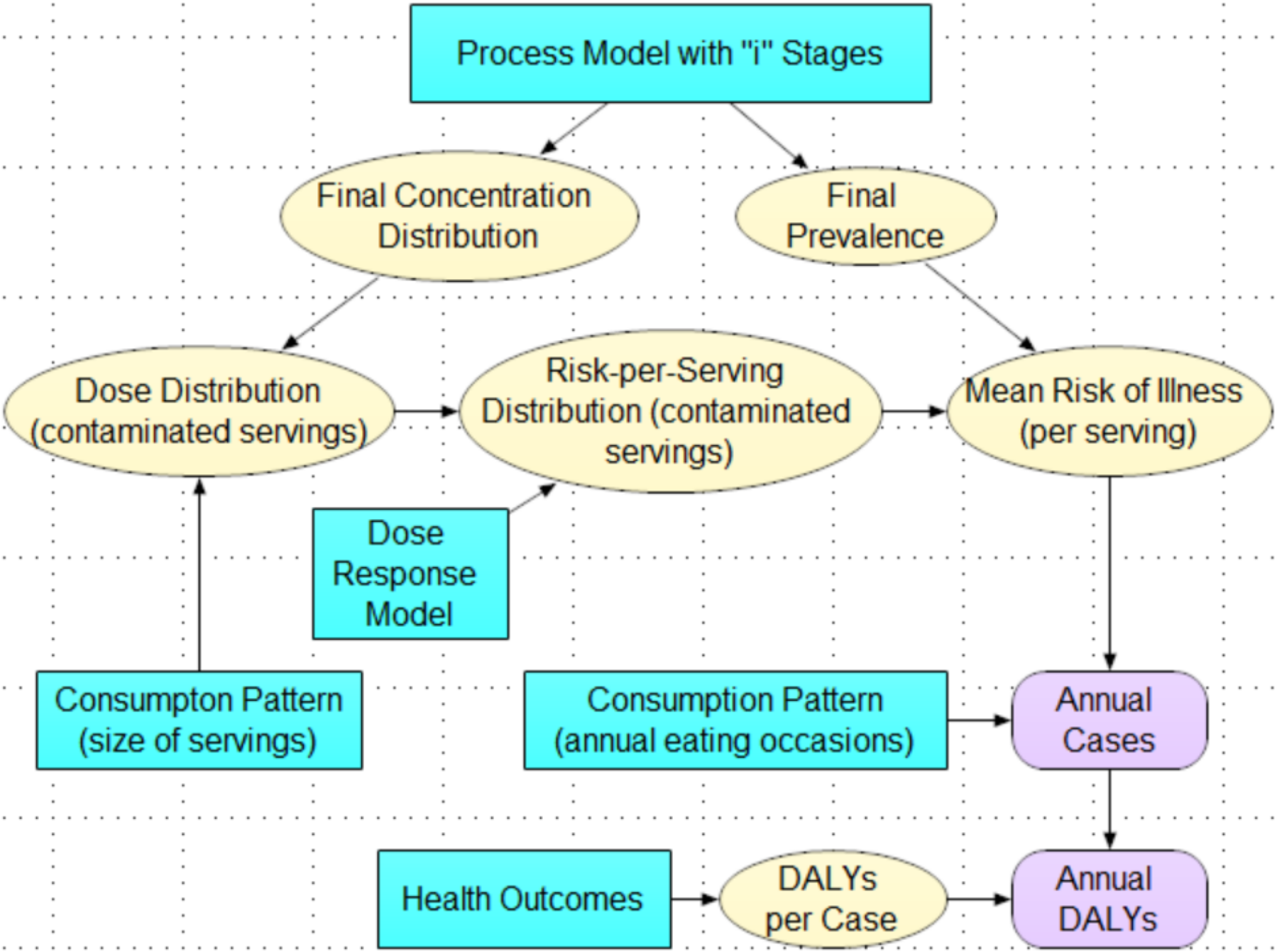
Process Model with "i" Stages
Final Concentration Distribution
Final Prevalence
Dose Distribution (contaminated servings)
Risk-per-Serving Distribution (contaminated servings)
Mean Risk of Illness (per serving)
Dose Response Model
Consumpton Pattern (size of servings)
Consumption Pattern (annual eating occasions)
Annual Cases
Health Outcomes
DALYs per Case
Annual DALYs

The scenarios…

- Looks at a specific situation: the illness risk associated with pathogenic E. coli (EHEC) contamination of irrigation water used on a lettuce field harvested for fresh-cut.
- They quantify and compare the risks for six contamination scenarios, all assuming that additional risks of contamination are minimal and constant across the scenarios.

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The scenarios…

- Hazard identification: EHEC from irrigation water prior to harvest.
- Measurement of the hazard: based on levels of generic E. coli (Ec) detected in the irrigation water as an indicator,
  - Assumes 1:100 ratio of EHEC to Ec.
  - Also looks at ratios of 1:10 and 1:1

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Estimation of exposure

- Based on overhead irrigation of an industry-average one acre lot of lettuce.
- 127,000 servings of fresh-cut lettuce per acre at a range of 0-125 (average 40) g per serving
- 30% of all lettuce acreage is irrigated overhead at a rate of 13,500 gal/A
- 50% of the water hits the edible portion, and that the edible portion holds 2.5 mL water/g lettuce.

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Estimation of exposure

Deactivation after irrigation

- Estimates that EHEC dies on the lettuce at a rate of 0.11 to 2.44 (w/most likely 0.50) log CFU/g during 3-5 (most likely 4) days between final irrigation and harvest

Growth/deactivation post-harvest

- Neutral impact on overall risk in this example

Cross contamination from handling

- Minimum of -1 (i.e., 10-fold decrease), most likely 1 and maximum 4 logs/g increase in contamination due to mishandling at the point of service.

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Estimation of consumption

- Estimated 127,000 servings of fresh-cut lettuce per acre based on industry data of average production per acre, minus average culled and average not sold.

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Dose-response

- They use a Beta-Poisson distribution with alpha 0.248, beta 48.80, based on published studies. This number is pathogen specific, independent of the commodity. Any calculation on EHEC would use the same distribution; other pathogens could have a different distribution shape and parameters

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Total DALYs

- Disability Adjusted Life Years: They use estimates from published studies on health impacts from the symptoms of EHEC infection, including the frequency of non-hospitalized illness, hospitalized illness (e.g., bloody diarrhea and HUS) and death per illness event, multiplied by the calculated average number of illness events.

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The scenarios, all in MPN Ec/100 ml

- Farm A, gross fecal contamination: 10,000 to 30,000
- Farm F, very high contamination: 700 to 4840
- Farm E, high contamination: 700 to 2420
- Farm B, moderate contamination: 50 to 700
- Farm D, low contamination, compliant with the proposed water quality standard: 50 to 235
- Farm C, no contamination introduced from irrigation (baseline).

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Conclusions on risk…

Scenario	Final Concentration (log cfu or pfu/g microbial, g/g chemical)	Final Prevalence	Mean Risk of Illness	Total EO or Consumers	Total DALYs
EHEC in Lettuce Fresh-Cut from Farm A (1:100 EHEC vs. E. coli)	-0.69	0.11	0.0042	1.3E+5	200
EHEC in Lettuce Fresh-Cut from Farm F (1:100 EHEC vs. E. coli)	-0.24	0.00073	9.3E-6	1.3E+5	0.44
EHEC in Lettuce Fresh-Cut from Farm E (1:100 EHEC vs. E. coli)	-0.19	0.00034	3.5E-6	1.3E+5	0.17
EHEC in Lettuce Fresh-Cut from Farm B (1:100 EHEC vs. E. coli)	-0.039	9.4E-6	9.9E-8	1.3E+5	0.0047
EHEC in Lettuce Fresh-Cut from Farm D (1:100 EHEC vs. E. coli)	-0.024	5.6E-6	8.5E-8	1.3E+5	0.0041
EHEC in Lettuce Fresh-Cut from Farm C (Baseline)	-0.016	4.4E-6	7.8E-8	1.3E+5	0.0037

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Conclusions on risk…

Table 1. Impact of Irrigation Water Quality on Predicted Illnesses [a]

Farm Description [b]	Predicted Cases per Acre
Gross contamination of irrigation water (Farm A)	546.0
Very high contamination of irrigation water (Farm F)	1.209
High contamination of irrigation water (Farm E)	0.455
Moderate contamination of irrigation water (Farm B)	0.0129
Low contamination, in compliance with proposed standard for irrigation water (Farm D)	0.0111
No contamination of irrigation water (Farm C, baseline)[c]	0.0101

[a] Predicted illnesses associated with the consumption of fresh-cut lettuce harvested from different one-acre farms, irrigated by overhead sprinkler 3-5 (most likely 4) days prior to harvest.

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What data does Y commodity need?

Exposure of Y to pathogens from water

- Pathogen of concern (prevalence X survival)
- Min/mode/max levels in water (indicator?)
- % of all Y acreage irrigated overhead (or other direct water contact preharvest)
- Frequency of irrigation
- Gallons/acre/irrigation event
- % of the water that hits the edible portion
- mL of water that sticks to the edible portion
- Last contact with water preharvest (days)

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What data does Y commodity need?

Growth/deactivation pre-, post-harvest

- Fate on Y in the field (min/mode/max rate of pathogen death under range of conditions)
  - % of Y exposed to those conditions
- Fate on Y post-harvest (any treatments that may increase/decrease levels?)
  - % of Y exposed to those treatments
- Effect of removing non-edible portion (min/mode/max)
- Cross contamination from handling
- Consumer handling practices

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What data does Y commodity need?

Estimation of consumption

- Servings of Y per year
- Size of a serving (min/mode/max)

Dose-response and DALYs

- Can use FDA's numbers if EHEC
- Numbers for other pathogens available

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Putting it all together

- Use the same calculations as FDA did
  - Work with the same FDA scientists
- Compare the DALYs results to baseline estimate
- If DALYs calculated for Y are at or lower than in the QRA, then the scenario provides the same or better estimated level of public health protection

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Comments / Questions?

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