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Supplementary materials

Table S1. Estimated prevalence and levels of *L. monocytogenes* in RTE food groups

Commodity Group ^a	Prevalence (based on 25 g units)	Between-lot Concentration Distribution (log ₁₀ CFU/g) ^b
Dairy Commodities	0.148% [0.064-0.291%] (8/5410) ^a	Normal(-2.47, 3.81)
Produce Commodities	0.445% [0.300-0.634%] (30/6749)	Normal(-0.34, 1.83) ^c
Seafood Commodities	0.573% [0.296-0.998%] (12/2095)	Normal(1.17, 1.39)
Other Commodities ^c	0.612% [0.419-0.862%] (32/5232)	Normal(-0.34, 1.83) ^c

^a The bracket indicates the 95% confidence interval determined using the method described in the interagency FDA-FSIS-ARS survey (Luchansky et al.,2017), and the parenthesis indicates the number of positive samples/total number of samples. A range of seafood, dairy, fresh produce and other commodities were included in the survey, where a stratified sampling plan with consideration of consumption and several other factors were used to select products for testing. For example, the seafood commodities included smoked seafood, seafood salads, and fresh crab meat (not pasteurized) and sushi containing raw fish; the produce commodities included raw cut vegetables, low-acid cut fruits and sprouts; the dairy commodities included fresh cheeses, soft-ripened cheeses and semisoft cheeses; the produce commodities included raw cut vegetables, low-acid cut fruit and sprouts; the other commodities included data for deli salads without meat and sandwiches.

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^b The distribution is truncated at maximum 6.14 log₁₀ CFU/g (the observed maximum in the FDA-ARS-FSIS Survey). Data from the interagency FDA-ARS-FSIS Survey (Luchansky et al., 2017) was used to derive the between-lot concentration distribution, except for the Dairy Commodities Group, for which data from the survey conducted by the National Food Processors Association (the NFPA Survey) of similar scope and study design (Gombas et al., 2003) was also used because of the relatively small number of positives and the large variability in the level for dairy samples from the FDA-ARS-FSIS Survey.

NFPA study: Fresh soft cheeses, Blue-veined cheeses, and mold-ripened cheeses

^c One between-lot distribution was derived from the combined data for produce and other commodities because of the similarity between the frequency distributions for Produce Commodities and that for Other Commodities (Figure S1).

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Table S2. Model inputs in FDA-iRISK and FDA-LmQRA App for *L. monocytogenes* in no-growth RTE Foods

Model Element	Model input	Reference
Process Model		
Initial contamination: prevalence and associated unit mass, and concentration.	Option 1. Prevalence=100% of lots (lot size=1,135 kg). Concentration distribution Normal(-2.5, 1.0) log ₁₀ CFU/g to represent the between-lot distribution. Alternatively, concentration distributions shown in Table 2 and Table 3B were used. Option 2. Prevalence=1.1% of units (e.g., unit size=25 g). Concentration distribution Triangular(-1.4, -1.4, 3.1) log ₁₀ CFU/g represent the between-lot distribution. Alternatively, prevalence and concentration distributions shown in Table S1 were used.	Analysis in this study of data reported in Luchansky et al., 2017 and Gombas et al., 2003
Process step: Sampling	Option 1. OC curves data for various sampling plans, by using the ICMSF spreadsheet program 10, based on within-lot s.d.=0.8 log ₁₀ , to obtain the probability of acceptance and corresponding log ₁₀ (arithmetic count/g) for the OC curves. Examples shown in Figure S2. Alternatively, using the FDA-OC App, we generated OC curves based on within-lot s.d.=0.4 or 1.2 log ₁₀ to evaluate the impact of changing the s.d. on relative risk	ICMSF, 2020; Pouillot et al., 2024a

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Model Element	Model input	Reference
	reduction for selected risk scenarios. Given the same within-lot s.d. (e.g., 0.8), the FDA-OC App generated the same OC curve output as that obtained from the ICMSF spreadsheet.	
	Option 2. Within-lot lognormal distribution with an arithmetic mean sampled from the between-lot distribution and s.d. of 0.8 log ₁₀ CFU/g.	This study
	Option 3. Within-lot contamination defined by two lognormal distributions: a higher-level distribution that defines the proportion of exceptional contamination defined in Table 4A and Table 4B; and a low-level lognormal distribution with an arithmetic mean sampled from Normal(-4.85, 1.0) log ₁₀ CFU/g and s.d. of 0.8 log ₁₀ CFU/g that defines contamination in the remaining samples within the lot.	This study
Consumption		
Model		
Serving size	50 g or 113g	This study

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Model Element	Model input	Reference
Number of servings	<p>1.0x10⁹. We selected 1 billion servings for the risk scenario based on consumption estimates in the U.S. population reported in the FDA/FSIS 2003 <i>L. monocytogenes</i> risk assessment, e.g., the number of servings consumed per year for the total population is 1 to 10 billion servings for combined fresh cheese, soft-ripen cheese, and semi-soft cheese; 10 to 11 billion servings for fresh fruits and vegetables; 0.1 to 1 billion servings for seafood; and more than 10 billion servings for deli-type salads. For the elderly population, the estimate for the number of servings consumed per year was approximately 10-fold less than that for the total population (Table III-2 in FDA/FSIS, 2003). In a recent risk ranking study (FDA, 2022), analysis of 2011-2016 consumption data from the National Health and Nutrition Examination Survey What We Eat in America database suggested a similar or greater number of servings consumed for the RTE food categories based on estimated consumption rates in the U.S. population.</p>	<p>This study; FDA/FSIS, 2003; FDA, 2022</p>
Dose Response		
Model		

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Model Element	Model input	Reference
65+ subpopulation	Option 1. Exponential dose response curve with r-value = 1.49×10^{-10} . Probability of adverse effect given response 100%.	Pouillot et al., 2015
Whole population	Option 2. Exponential dose response curve with r-value (marginal across all subpopulations) = 1.19×10^{-10} . Probability of adverse effect given response 100%.	Pouillot et al., 2015
	Option 3. Exponential dose response curve with r-value (marginal across all subpopulations) = 1.25×10^{-11} . Probability of adverse effect given response 100%.	Pouillot et al., 2024b

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Table S3. Performance of 2-class and 3-class mixed sampling plans based on ICMSF methodology*

<i>n</i>	<i>c</i>	<i>m</i> (CFU per X g)	<i>M</i> (CFU/g)	Arithmetic mean* (CFU/g)
10	1	0/5 g	20	0.36
10	1	0/25 g	20	0.072
5	1	0/25 g	500, 100, 20, or 10	0.32
5	3	0/25 g	20	2.65
10	0	0/5 g	NA	0.15 (1 CFU/6.5 g)
10	0	0/25 g	NA	0.031 (1 CFU/32.6 g)
5	0	100/g	NA	434.3
5	0	0/25 g	NA	0.10 (1 CFU/10 g)

* Based on ICMSF spreadsheet standard program 10 (ICMSF, 2020). Performance defined as the arithmetic mean concentration, which is the arithmetic mean of a lognormal distribution with s.d. of 0.8, that is detected with a 95% probability.

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Table S4. Estimated prevalence of *L. monocytogenes* in RTE food groups

Commodity Group	Prevalence		No. positives >20 CFU/g	Total No. positives	Percent of	Percent of
	among 25 g units	among 1,135 kg units (lots)			positives at >20 CFU/g	samples at >20 CFU/g ^b
Dairy	0.148%	100%	3	8	37.5%	0.055% ^c
NFPA ^a	NA	NA	4	42	9.5%	
Interagency & NFPA			7	50	14.0%	
Produce	0.445%	100%	3	30	10.0%	0.044%
Seafood	0.573%	100%	4	12	33.3%	0.19%
Other Commodities	0.612%	100%	6	32	18.8%	0.11%

^a Data from the interagency FDA-ARS-FSIS Survey (Luchansky et al., 2017) was used to derive the prevalence estimates, and the percent of positive samples at ≥ 20 CFU/g. For the Dairy Commodities Group, data from the NFPA Survey of similar scope and study design (Gombas et al., 2003) was also used to determine the percent at >20 CFU/g because of the relatively small number of positives and the large variability in the level for dairy samples from the FDA-ARS-FSIS Survey.

^b Percentage calculated as follows: 3/5410 for dairy (total 5,410 samples and 3 samples had a level >20 CFU/g), 3/6749 for produce, 4/2095 for seafood, and 6/5232 for other commodities.

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^c The estimates here, e.g., 0.055%, do not appear consistent with that would be predicted from the between-lot distributions in Table S1, e.g., Normal(-2.47, 3.81) for the dairy commodities. The estimates here were used to somewhat anchor our assumptions for the proportion of exceptional contamination to consider in this study. However, there is a lack of enumeration data and we did not attempt to delineate the complex relationship of between-lot variability and within-lot variability for commodities in the food supply.

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Table S5. Alternative scenario based on 10% contaminated lots and dose response model by Pouillot et al., 2015: Predicted cases per one billion servings of commodity groups and relative risk reduction (RRR) for the whole population ^a

Sampling Plan				Dairy Commodities			Produce Commodities			Seafood Commodities			Other Commodities		
<i>n</i>	<i>c</i>	<i>m</i>	<i>M</i>	Cases_	% Lots	RRR	Cases_T	% Lots	RRR	Cases	% Lots	RRR	Cases	% Lots	RRR
				Test	Rejected		est	Rejected		_Test	Rejected		_Test	Rejected	
10	1	0 CFU/5 g	20 CFU/g	21.8	0.190%	1.16	3.91	0.663%	1.54	8.94	1.93%	1.76	4.68	0.936%	1.84
10	1	0 CFU/5 g	100 CFU/g	21.8	0.146%	1.16	3.99	0.485%	1.51	9.28	1.47%	1.69	4.80	0.725%	1.79
5	0	0 CFU/25 g	NA	23.5	0.252%	1.08	4.84	1.28%	1.24	11.7	2.31%	1.34	6.33	1.72%	1.36
10	0	0 CFU/5 g	NA	21.8	0.398%	1.16	3.85	1.84%	1.56	8.70	3.69%	1.81	4.58	2.41%	1.88

^a Not considering growth between retail and consumption. Without testing the predicted number of cases per billion servings was 25.3 for Dairy Commodities, 6.02 for Produce Commodities, 15.7 for Seafood commodities, and 8.62 for Other Commodities; Dose response model marginal across all subpopulations; serving size 50 g (0.11 lb). *L. monocytogenes* contamination: between-lot concentration distributions as in Table S1; prevalence at the unit level in contaminated lots: 1.48% for Dairy Commodities, 4.45% for Produce Commodities, 5.73% for Seafood commodities, and 6.12% for Other Commodities; lot size=10,000 units; s.d.=0.8 log₁₀ CFU/g for within-lot distributions. Sampling and testing all lots, and if positive replace the lot with a noncontaminated lot. Enumeration (when performed) is done using MPN (3 tubes of 10, 1, 0.1, and 0.01g) and is only on samples tested positive in detection. Model simulation 10 K iterations.

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Table S6. Predicted cases per billion servings comparing no-growth foods and growth foods*

S6-A. Exceptional contamination 1% samples at 20 CFU/g

RTE Foods	No Test	Test using 2-class plan	Test using 3-class mixed plan
		($n=10, m=0/5$ g, $c=0$)	($n=10, m=0/5$ g, $M=20$ CFU/g, $c=1$)
No Growth	1.18	1.06	1.10
Growth 1 log	10.8	9.67	10.1
Growth 2 log	89.5	80.2	83.5

S6-B. Exceptional contamination 1% samples at 100 CFU/g

RTE Foods	No Test	Test using 2-class plan	Test using 3-class mixed plan
		($n=10, m=0/5$ g, $c=0$)	($n=10, m=0/5$ g, $M=20$ CFU/g, $c=1$)
No Growth	5.58	5.01	5.04
Growth 1 log	47.9	42.9	43.2
Growth 2 log	363	326	328

* Predicted risk for foods that do not supporting *L. monocytogenes* growth (“no-growth” foods) and those do (“growth” foods) with and without testing. *L. monocytogenes* contamination for between-lot distribution: Normal(-4.85, 1.0) log₁₀ CFU/g;

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prevalence=100% of lots (lot size=10,000 units); dose response model (Pouillot et al., 2015): marginal across all subpopulations; serving size 50 g (0.11 lb). Sampling and testing all lots, and if positive replace the lot with a noncontaminated lot. Enumeration (when performed) is done using MPN and is only on samples tested positive in detection. Model simulation 10 K iterations. Within-lot contamination defined by two lognormal distributions: a higher-level distribution that defines the proportion of exceptional contamination at 20 CFU/g of 1% (Table S6-A) or at 100 CFU/g of 1% (Table S6-B); and a low-level lognormal distribution with an arithmetic mean sampled from Normal(-4.85, 1.0) log and s.d. of 0.8 log₁₀ CFU/g that defines contamination in the remaining samples within the lot.

Supplemental figure legends:

Figure S1. Distribution of *L. monocytogenes* concentrations in samples of RTE foods at retail from the U.S., in which the organism was detected in Dairy (8/5410, i.e., 8 positives of total 5,410 samples), Seafood (12/2095), Produce (30/6749), and Other commodities (32/5232), using data from an interagency market basket survey (LmMBS; Luchansky et al., 2017). A positive sample was positive in 25 g, and each positive sample was enumerated. The concentration distribution is shown as the number of positive samples found ranging from -1.5 to 6.5, corresponding to [(-2) - (-1)] to [6 - 7], log₁₀ MPN/g or log₁₀ CFU/g, in each of the 1-log₁₀ concentration ranges. These frequency distributions were used to derive the between-lot concentration distributions for the various

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commodity group and used to evaluate the impact of sampling. For the Dairy Commodities Group, combined data from the interagency LmMBS and the NFPA market basket survey conducted earlier in the U.S. (Gombas et al., 2003) was used to derive the between-lot distribution because of the relatively small number of positives and the large variability in the level for dairy samples from the interagency LmMBS.

Figure S2. OC curves obtained from the ICMSF spreadsheet standard program 10 (ICMSF, 2020): (A) 3-class mixed plans with varying $c=1, 2$ or 3 ; (B) 3-class mixed plans with varying $M=500, 100, 20,$ or 10 CFU/g; (C) 3-class mixed plans with changing n and c , and a 2-class plan as indicated.; (D) 3-class mixed plans with varying $n=10, M=20$ CFU/g with vary c ($c=1$ or 2) and varyng m ($m=0/5$ g or $0/25$ g). Within-lot s.d.= $0.8 \log_{10}$ was used for all the sampling plans to obtain the probability of acceptance and corresponding \log_{10} (arithmetic count/g) for the OC curves.

Figure S3. Predicted cases per billion servings and relative risk reduction (RRR) for no-growth RTE foods as influenced by the proportion of lots subject to testing: 2-class plan $n=10$ $m=0/5$ g $c=0$ (blue) vs. 3-class mixed plan $n=10$ $m=0/5$ g $c=1$ $M=20$ CFU/g (orange).

Figure S1.

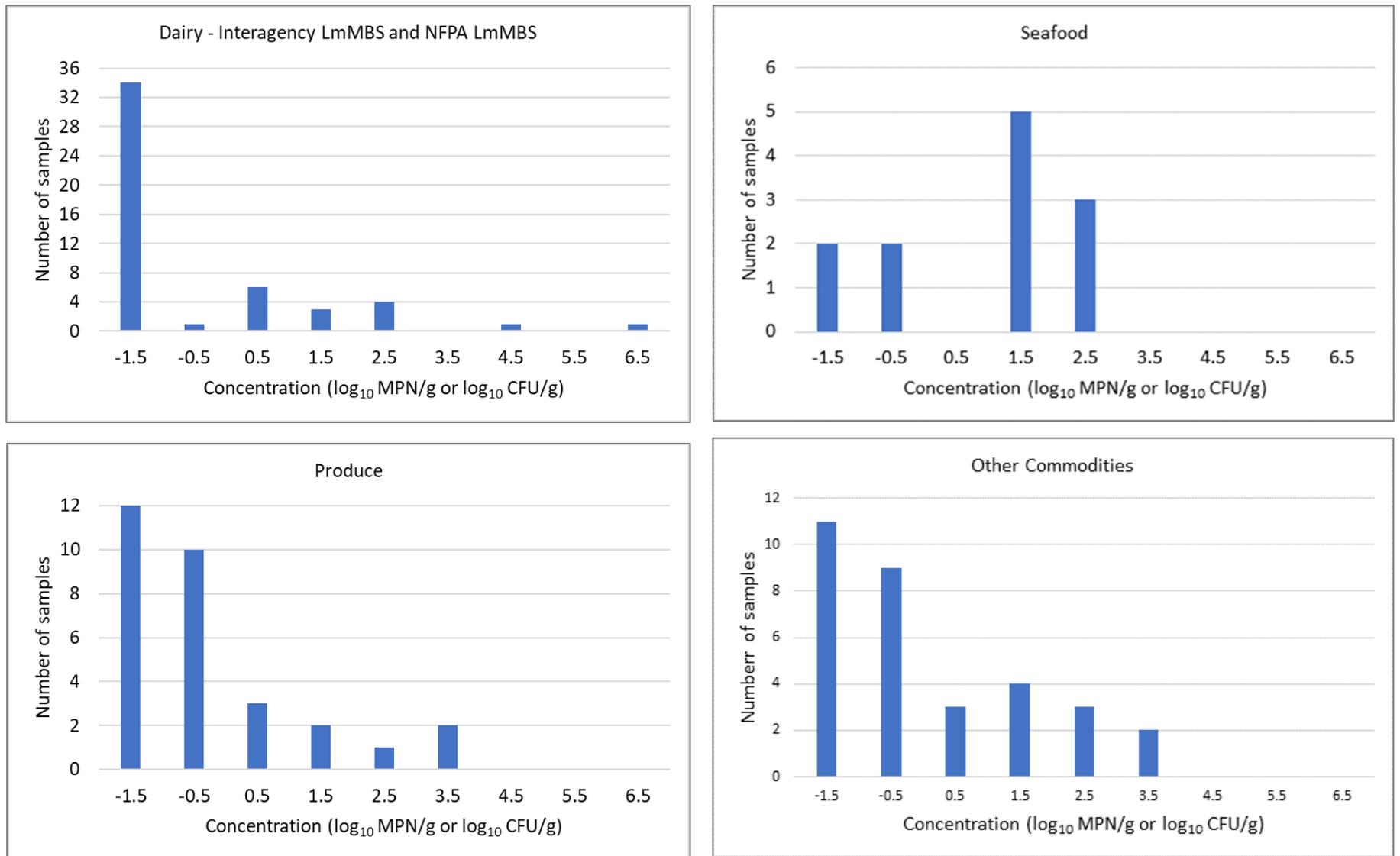


Figure S2.

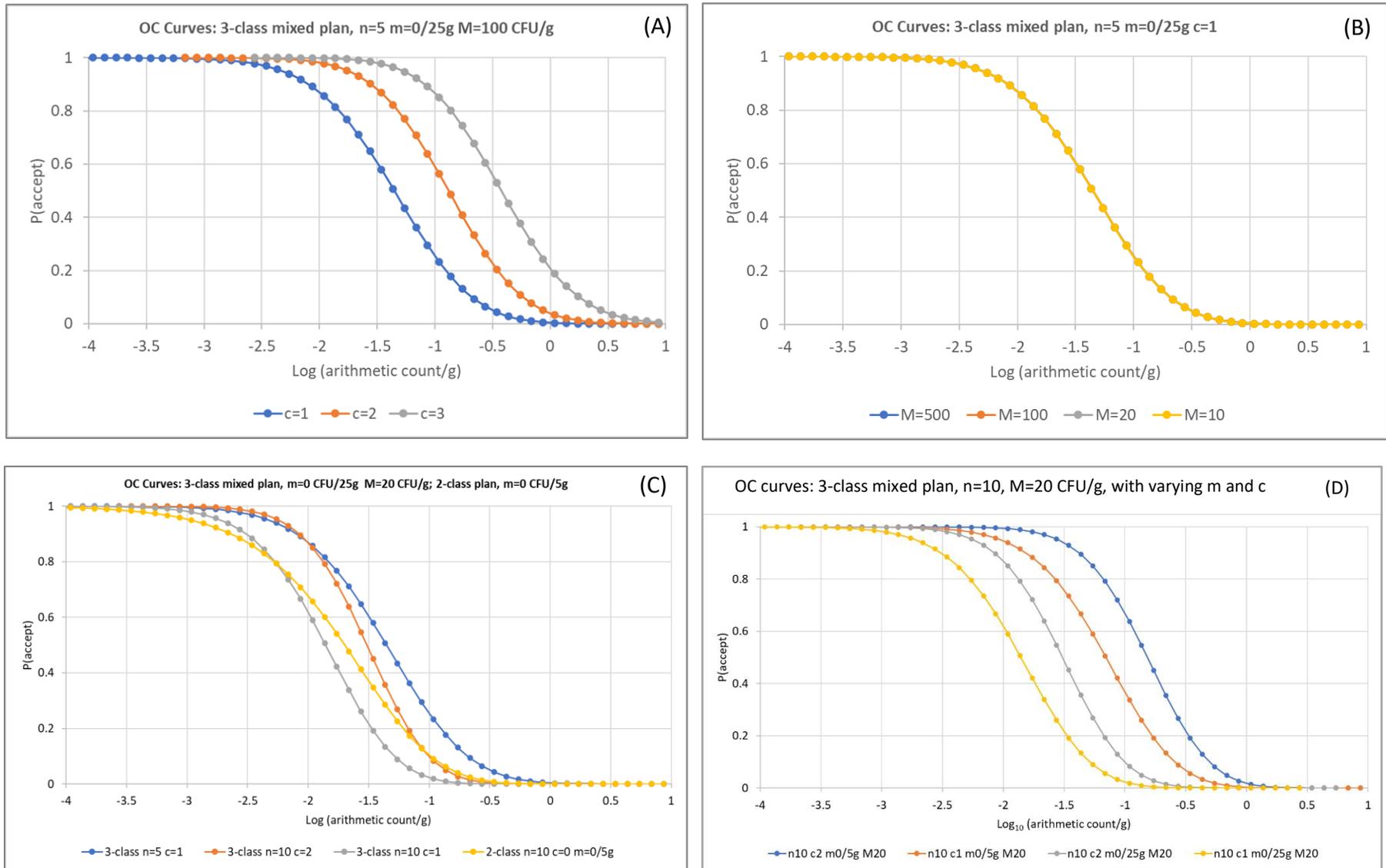


Figure S3.

