

Figure 1: Probability of detection observed by each of 18 laboratories for samples containing between zero and 0.2% meat and bone meal (MBM)

Probability of detection observed by 18 laboratories; 
  Probability of detection observed by 9 laboratories, 
  Probability of detection observed by 3 laboratories, 
  Probability of detection observed by 1 laboratory

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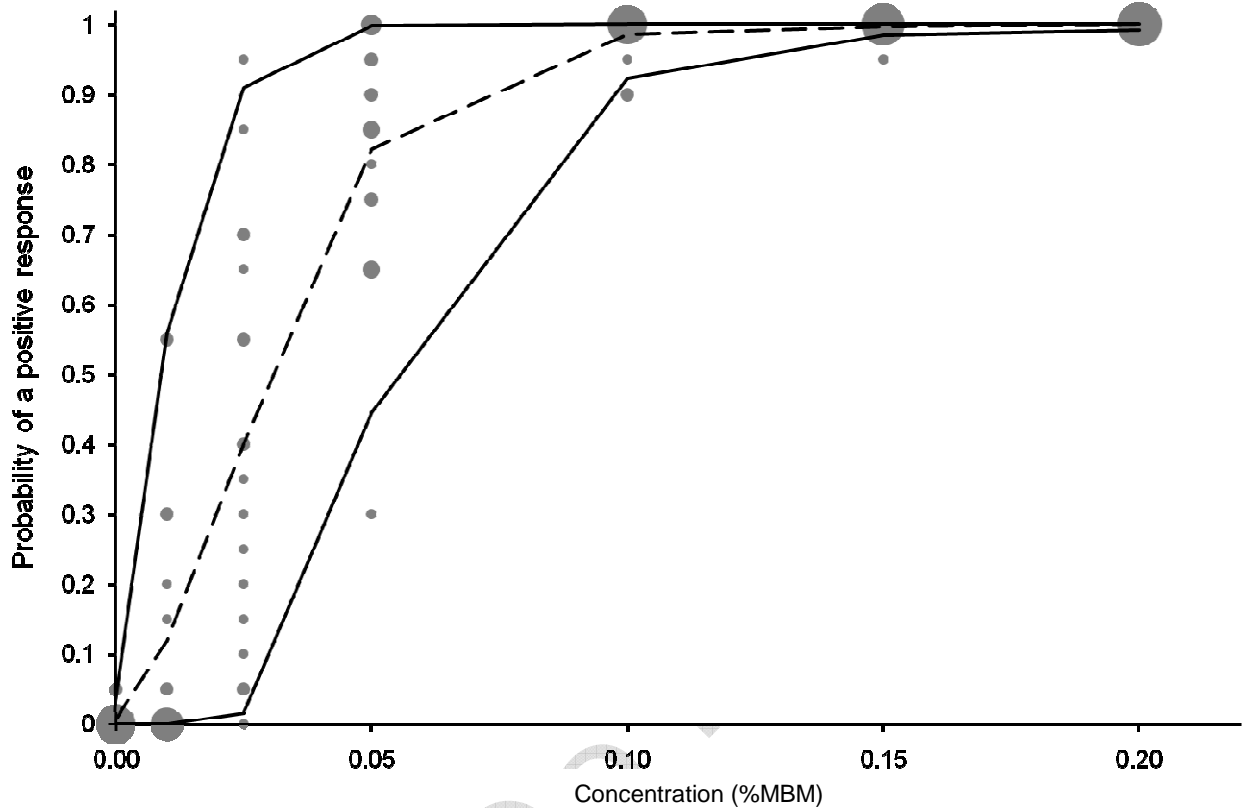


Figure 2: Probability of detection observed by each of 18 laboratories for samples containing between zero and 0.2% MBM with estimates of average probability of detection and the probability of detection for the 5<sup>th</sup> and 95<sup>th</sup> percentile of laboratories. ● Probability of detection observed by 18 laboratories; ● Probability of detection observed by 9 laboratories, ● Probability of detection observed by 3 laboratories, ● Probability of detection observed by 1 laboratory, — — — — Mean probability of detection, — — — — Lower (5%) and upper (95%) limits of a prediction interval for probability of detection in a laboratory.

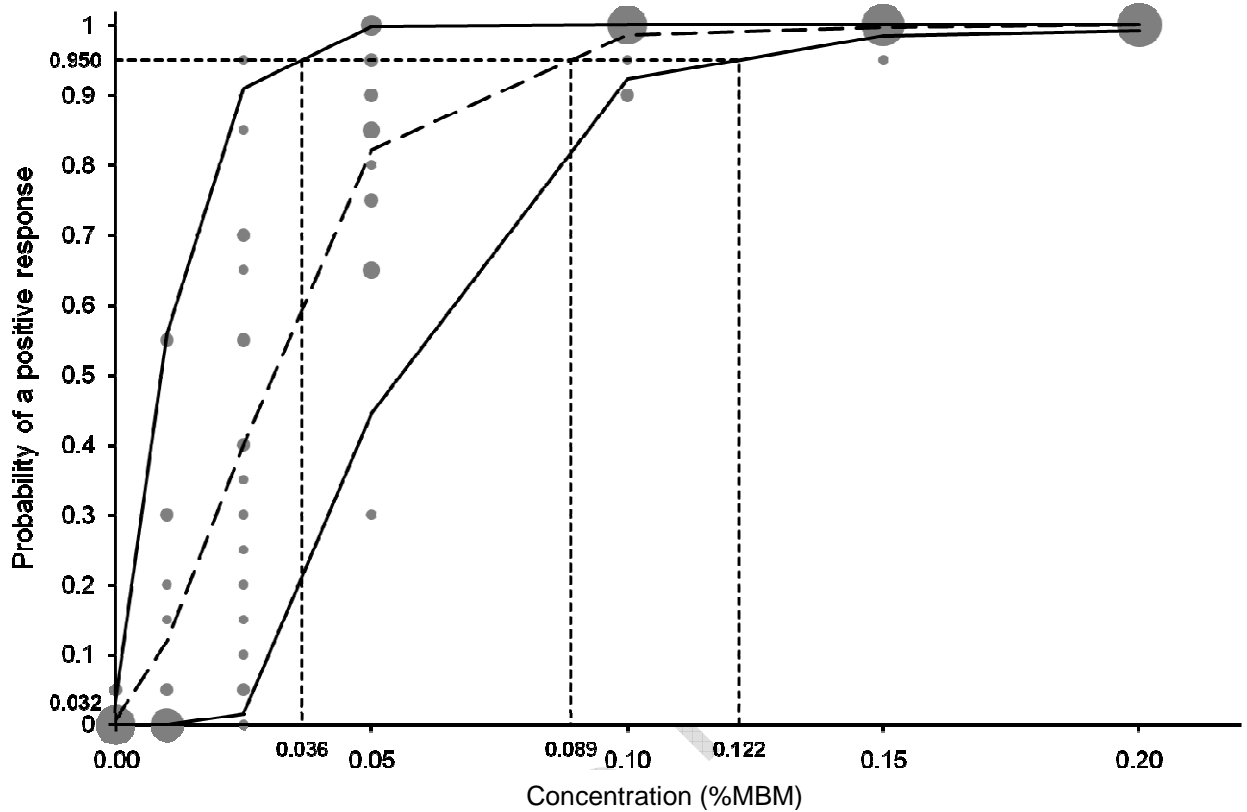


Figure 3: Estimates of an upper limit for the false positive probability prediction interval for the limit of detection for MBM. ● Probability of detection observed by 18 laboratories; ● Probability of detection observed by 9 laboratories, ● Probability of detection observed by 3 laboratories, ● Probability of detection observed by 1 laboratory, — — — — Mean probability of detection, — — — — Lower (5%) and upper (95%) limits of a prediction interval for probability of detection in a laboratory. - - - - - Projection from probability of detection=0.95 to give lower(5%), expected and upper (95%) limits of a prediction interval for limit of detection in a laboratory.

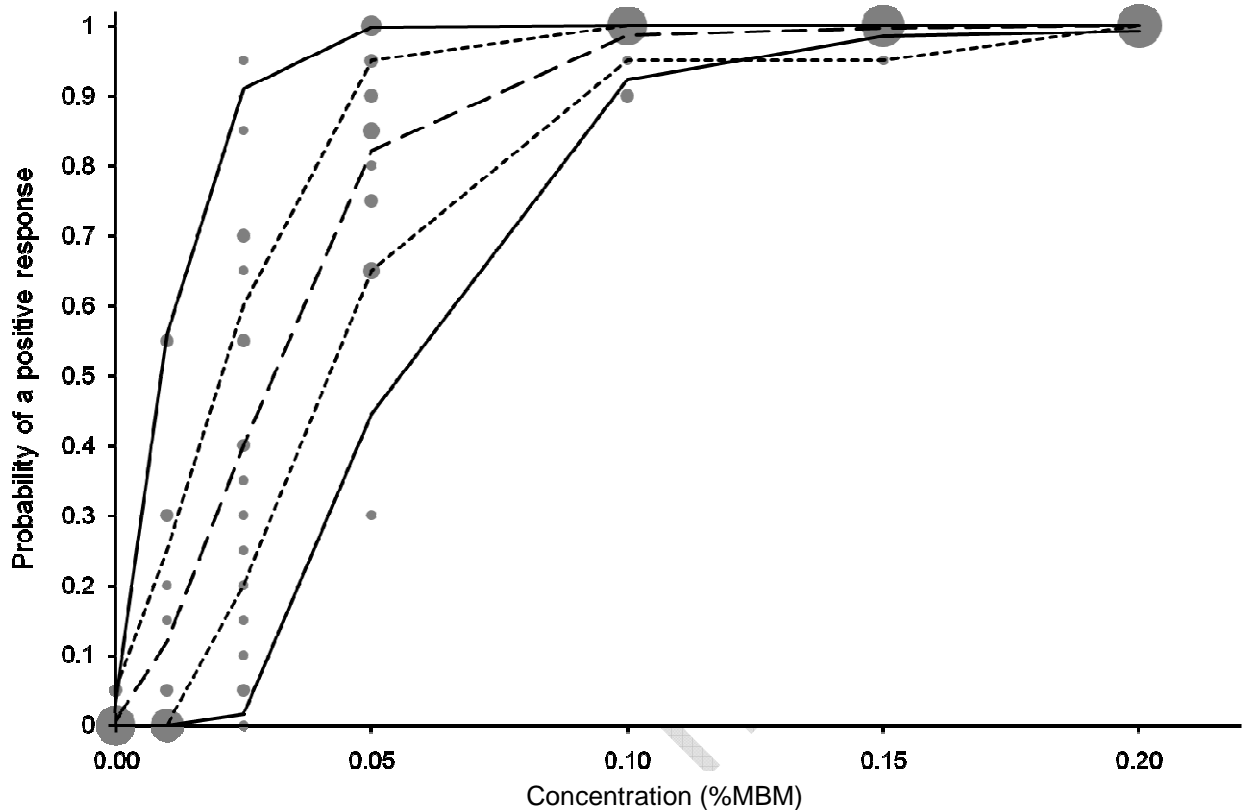


Figure 4: Comparison between the interval within which probabilities of detection lie and the interval that is given by the uncertainty associated with the use of a finite number of replicate analyses with no between-laboratory variation. ● Probability of detection observed by 18 laboratories; ● Probability of detection observed by 9 laboratories, ● Probability of detection observed by 3 laboratories, ● Probability of detection observed by 1 laboratory, — — — — Mean probability of detection, ————— Lower (5%) and upper (95%) limits of a prediction interval for probability of detection in a laboratory. - - - - - Lower (5%) and upper (95%) for observed probabilities of detection if all observations are consistent with the estimated mean probability of detection with no between-laboratory variation.

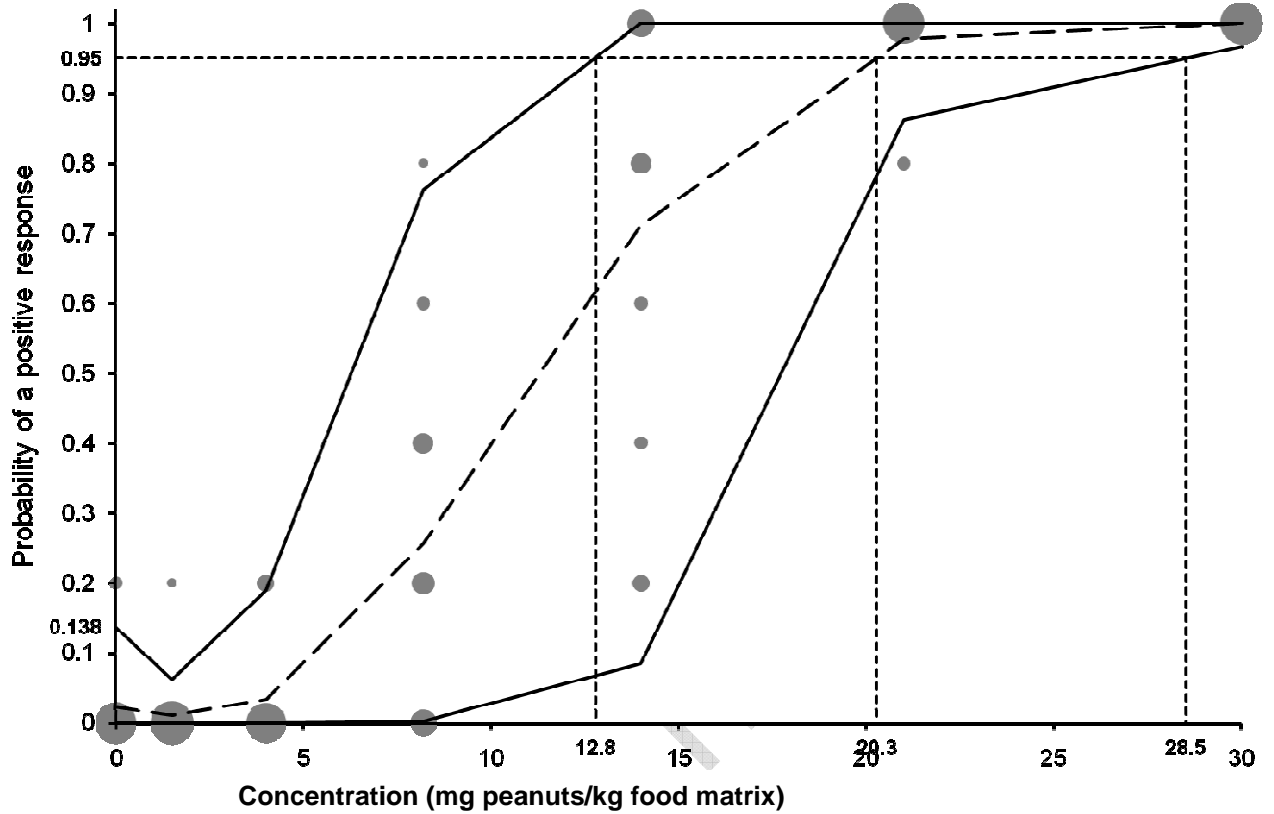


Figure 5: Estimates of an upper limit for the false positive probability and prediction interval for the limit of detection for peanut protein in cookies.

● Probability of detection observed by 18 laboratories; ● Probability of detection observed by 9 laboratories; ● Probability of detection observed by 3 laboratories; ● Probability of detection observed by 1 laboratory; — — — — Mean probability of detection; ————— Lower (5%) and upper (95%) limits of a prediction interval for probability of detection in a laboratory; - - - - - Projection from probability of detection=0.95 to give lower (5%), expected and upper (95%) limits of a prediction interval for limit of detection in a laboratory.

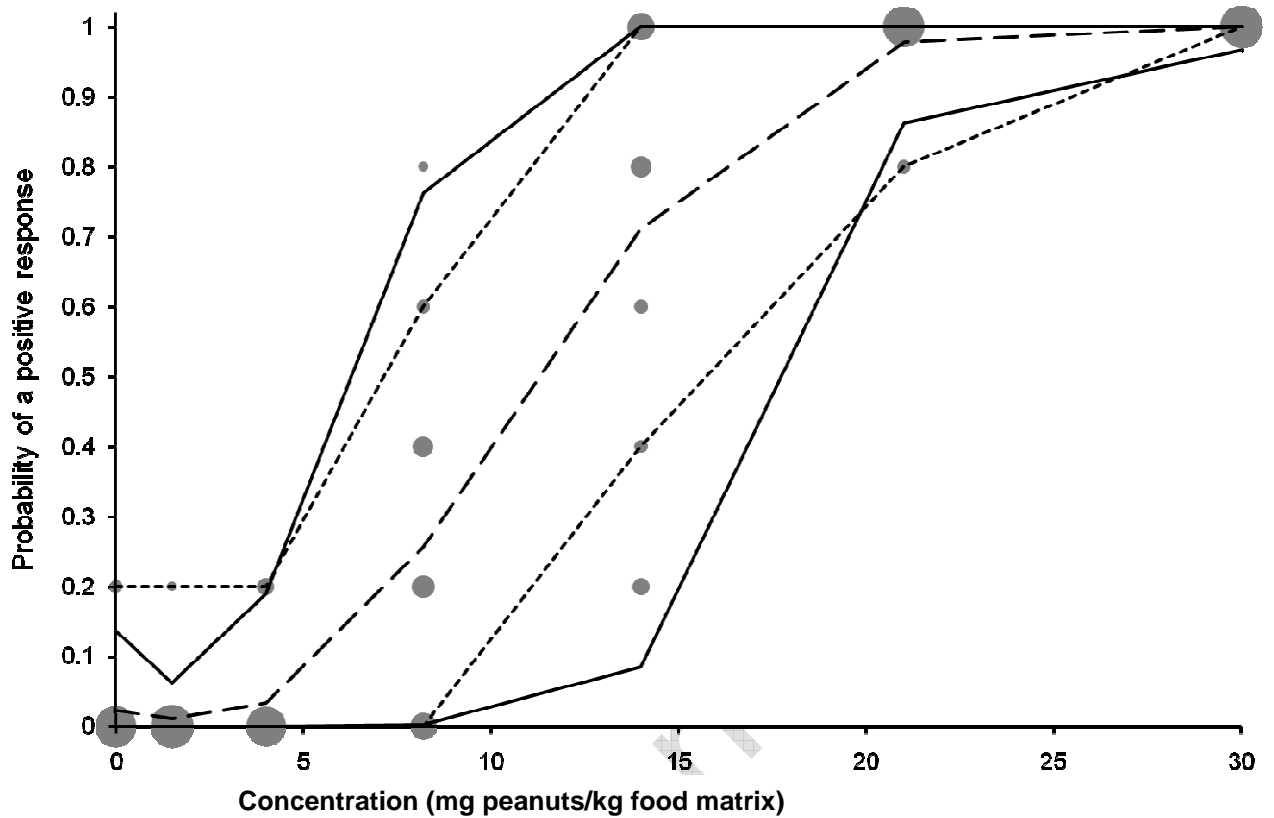


Figure 6: Comparison between the interval within which observed probabilities of detection lie and the interval that is consistent with the uncertainty associated with the use of a finite number of replicate analyses for a method to detect peanut protein in cookies. ● Probability of detection observed by 18 laboratories; ● Probability of detection observed by 9 laboratories; ● Probability of detection observed by 3 laboratories; ● Probability of detection observed by 1 laboratory; — — — — Mean probability of detection; — — — — Lower (5%) and upper (95%) limits of a prediction interval for probability of detection in a laboratory; - - - - - Lower (5%) and upper (95%) limits for observed probabilities of detection if all observations are consistent with the estimated mean probability of detection with no between-laboratory variation.

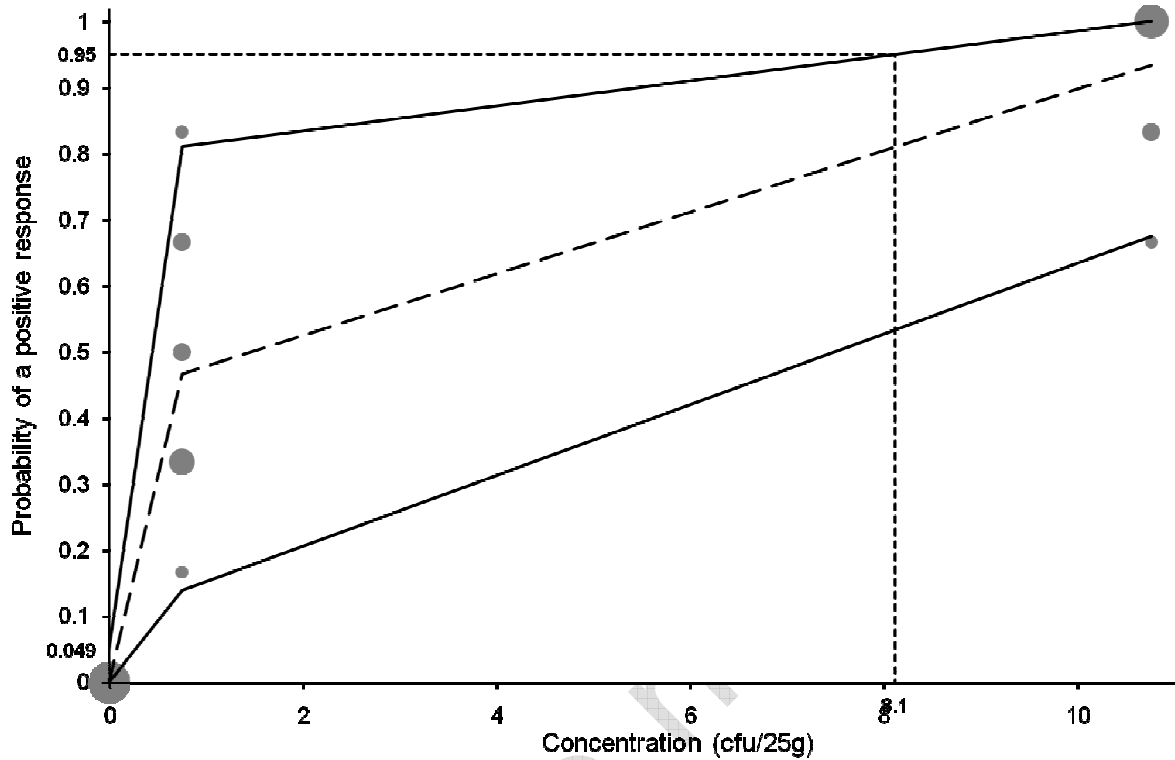


Figure 7: Estimates of an upper limit for the false positive probability and prediction interval for the limit of detection for salmonella in ground beef.

● Probability of detection observed by 6 laboratories; ● Probability of detection observed by 3 laboratories; ● Probability of detection observed by 1 laboratory; — — — — Mean probability of detection; — — — — Lower (5%) and upper (95%) limits of a prediction interval for probability of detection in a laboratory; - - - - - Projection from probability of detection=0.95 to give lower (5%), expected and upper (95%) limits of a prediction interval for limit of detection in a laboratory.

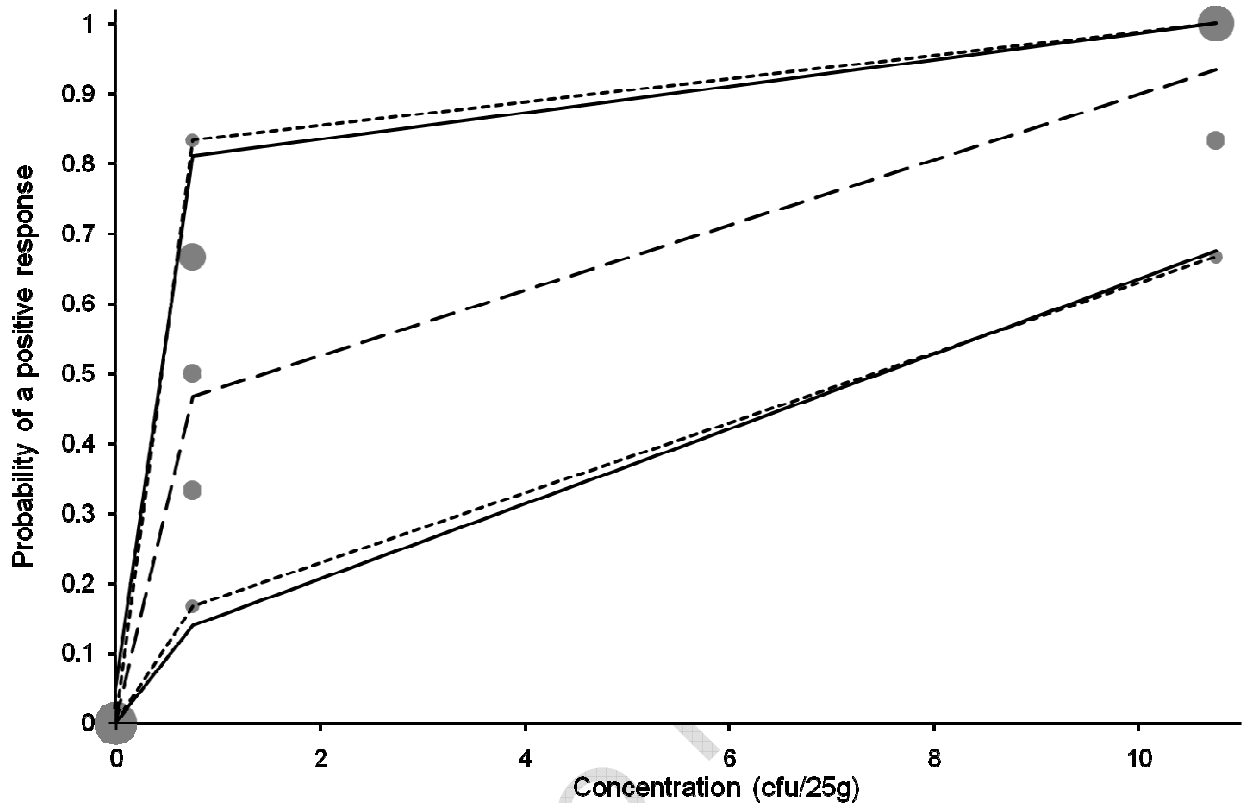
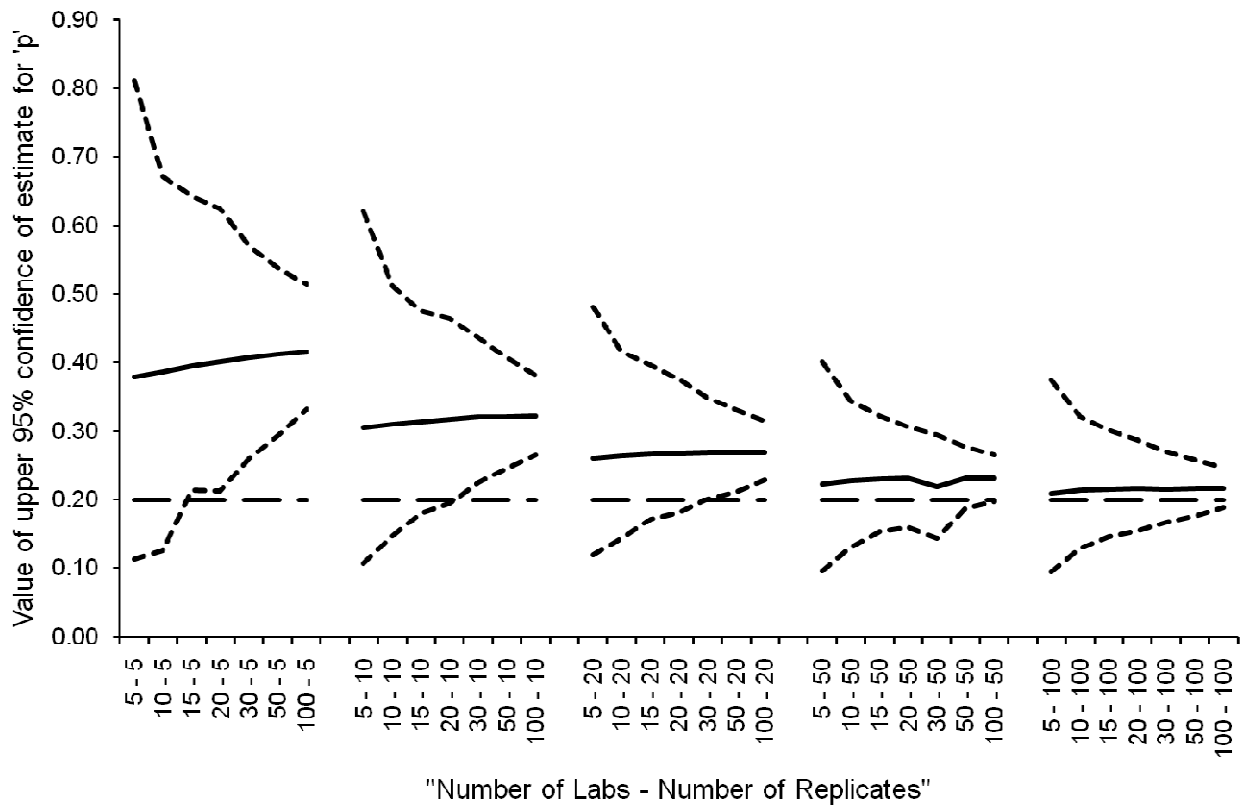


Figure 8: Comparison between the interval within which observed probabilities of detection lie and the interval that is consistent the uncertainty associated with the use of a finite number of replicate analyses for a method to detect salmonella in ground beef. ● Probability of detection observed by 6 laboratories; ● Probability of detection observed by 3 laboratories; ● Probability of detection observed by 1 laboratory; — — — — Mean probability of detection; — — — — Lower (5%) and upper (95%) limits of a prediction interval for probability of detection in a laboratory; - - - - - Lower (5%) and upper (95%) limits for observed probabilities of detection if all observations are consistent with the estimated mean probability of detection with no between-laboratory variation.

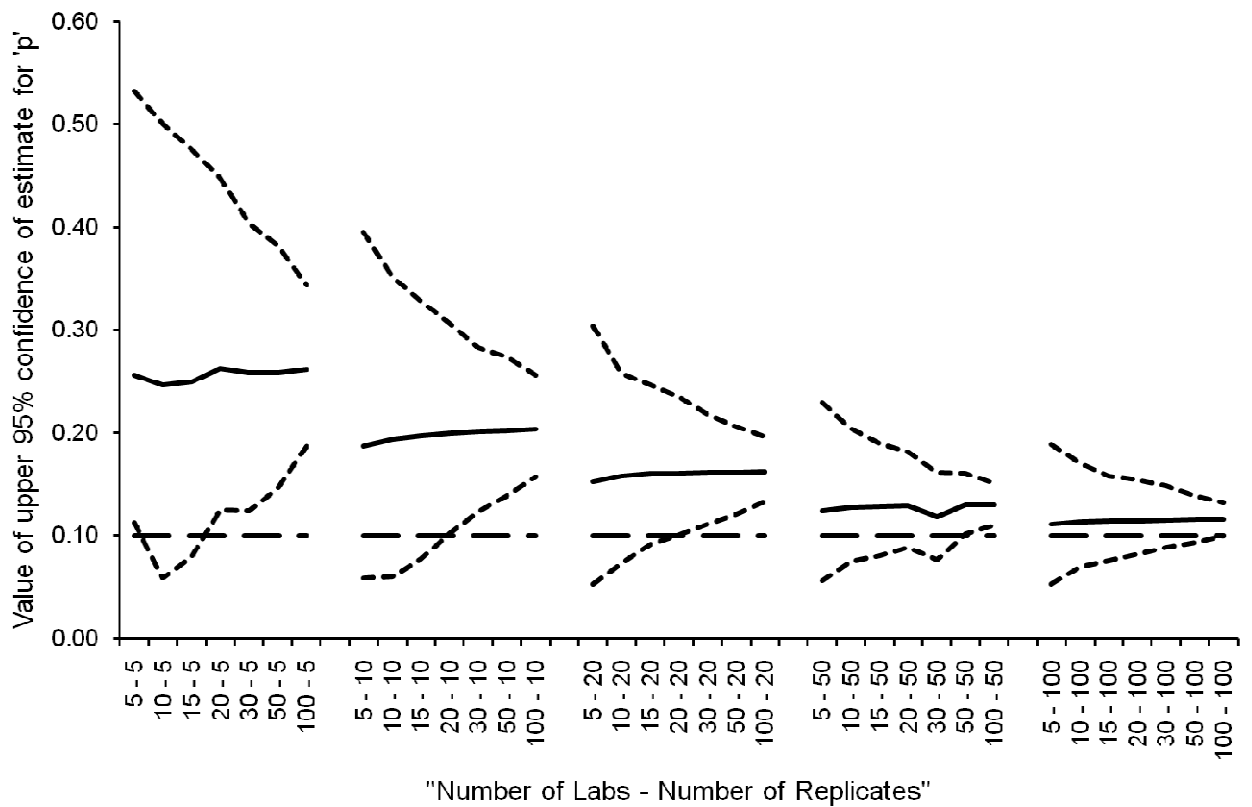
Figure 9: Upper 95% confidence for probability of detection where true 95th percentile = 0.20



- - - - True upper 95<sup>th</sup> percentile of simulated laboratories, \_\_\_\_\_  
 Average estimate of probability of positive for upper 95<sup>th</sup> percentile of  
 laboratories. \_\_\_\_\_ 5<sup>th</sup> and 95<sup>th</sup> percentile of estimates.

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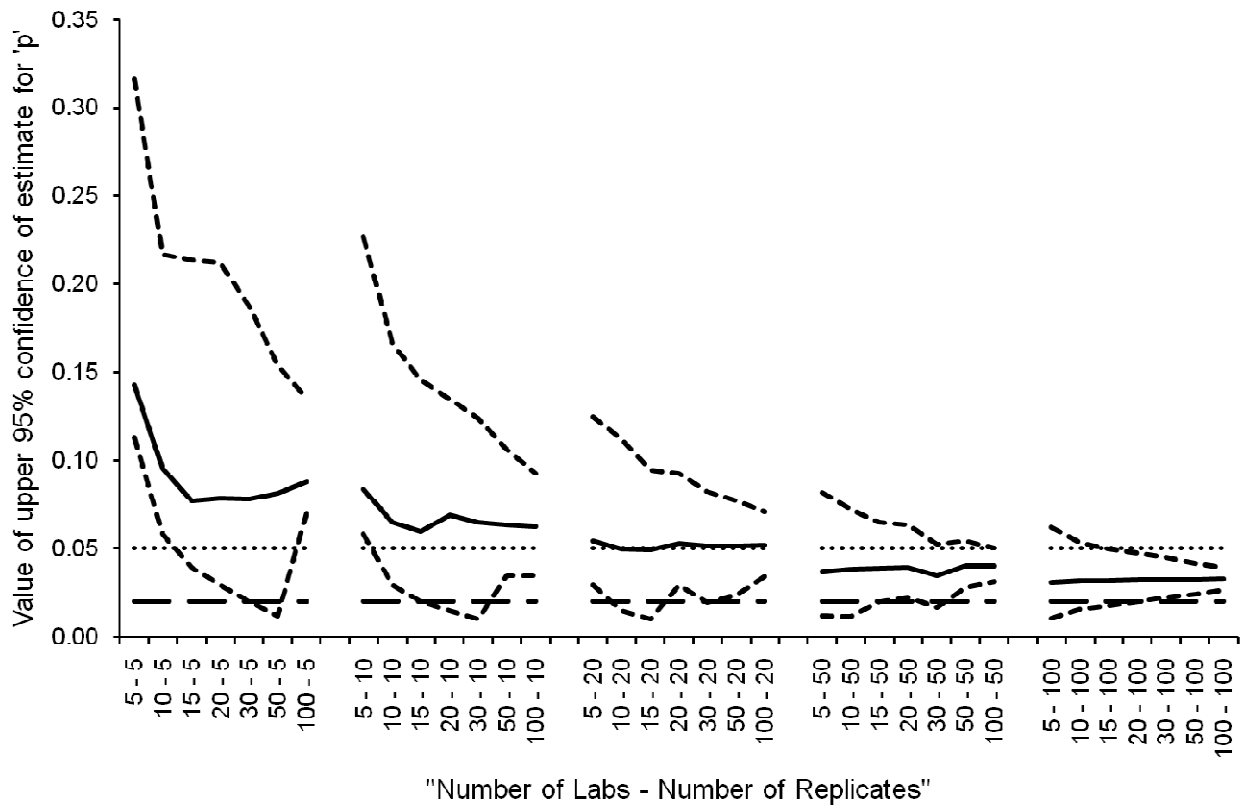
Figure 10: Upper 95% confidence for probability of detection where true 95th percentile = 0.10



- - - - True upper 95<sup>th</sup> percentile of simulated laboratories, \_\_\_\_\_  
 Average estimate of probability of positive for upper 95<sup>th</sup> percentile of  
 laboratories. - - - - 5<sup>th</sup> and 95<sup>th</sup> percentile of estimates.

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Figure 11 Upper 95% confidence for probability of detection where true 95th percentile = 0.02



- - - - True upper 95<sup>th</sup> percentile of simulated laboratories, \_\_\_\_\_  
 Average estimate of probability of positive for upper 95<sup>th</sup> percentile of  
 laboratories. - - - - 5<sup>th</sup> and 95<sup>th</sup> percentile of estimates. ....  
 'p'=0.05

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**Table 1: Results produced during the collaborative trial of a method for the detection of MBM in animal feed**

Concentration (% MBM)	Positive responses out of 20	Number of laboratories
0.000	0	16
0.000	1	2
0.010	0	10
0.010	1	2
0.010	3	1
0.010	4	1
0.010	6	2
0.010	11	2
0.025	0	1
0.025	1	2
0.025	2	1
0.025	3	1
0.025	4	1
0.025	5	1
0.025	6	1
0.025	7	1
0.025	8	2
0.025	11	2
0.025	13	1
0.025	14	2
0.025	17	1
0.025	19	1
0.050	6	1
0.050	13	3
0.050	15	2
0.050	16	1
0.050	17	3
0.050	18	2
0.050	19	2
0.050	20	4
0.100	18	2
0.100	19	1
0.100	20	15
0.150	19	1
0.150	20	17
0.200	20	18

**Table 2: Individual results reconstituted from result reported in Table 1 for samples containing 0.010% MBM**

“Lab”(i)*	Number of samples ( $n_i$ )	Number of positive results ( $x_i$ )	Estimate of probability of detection ( $p_i$ )
1	20	0	0
2	20	0	0
3	20	0	0
4	20	0	0
5	20	0	0
6	20	0	0
7	20	0	0
8	20	0	0
9	20	0	0
10	20	0	0
11	20	1	0.05
12	20	1	0.05
13	20	3	0.15
14	20	4	0.20
15	20	6	0.30
16	20	6	0.30
17	20	11	0.65
18	20	11	0.65

\*This just indicates that each set of results comes from a different laboratory

**Table 3: Estimates of statistical parameters used to describe performance of a method to detect MBM in animal feed**

Concentration (% MBM)	$N$	$X$	$\bar{p}(1)$	$s_R$	$\nu_s(2)$	$w_s(3)$	$\nu_h(4)$	$w_h(5)$
0	360	2	0.00556	0.0162	0.1118	20.02	2.5	358.5
0.010	360	43	0.1194	0.1872	0.2391	1.762	43.5	317.5
0.025	360	144	0.4000	0.2895	0.7453	1.118	144.5	216.5
0.050	360	296	0.8222	0.1792	2.919	0.6311	296.5	64.5
0.100	360	355	0.9861	0.0335	11.08	0.1561	355.5	5.5
0.150	360	359	0.9972	0.0118	18.89	0.05262	359.5	1.5
0.200	360	360	1.0000	0.0000	NC	NC	360.5	0.5

$N$ : Total number of analyses,  $X$ : total number of positive results;  $\bar{p}(1)$ : estimated mean probability of detection (Equation 1);  $s$ : standard deviation of estimates of probability of detection from the individual laboratories;  $\nu_s(2)$ : shape parameter of beta distribution based on mean and standard deviation of probability of detection (Equation 2);  $w_s(3)$ : shape parameter of beta distribution based on mean and standard deviation of probability of detection (Equation 3);  $\nu_h(4)$ : shape parameter of beta distribution based on  $N$  and  $X$  (Equation 4),  $w_h(5)$ : shape parameter of beta distribution based on  $N$  and  $X$  (Equation 5). **NC**: Not calculated.

**Table 4: Estimated lower (95%) and upper (5%) limits for the probability of detection in a laboratory using the method to detect MBM in animal feed**

Concentration (% MBM)	$L_s(6)$	$U_s(7)$	$L_h(8)$	$U_h(9)$	Lowerlimit (10)	Upperlimit (11)
0	7.3E-14	0.0323	0.00159	0.0153	7.3E-14	0.0323
0.010	1.7E-06	0.5588	0.0936	0.1498	1.7E-06	0.5588
0.025	0.0159	0.9102	0.3582	0.4430	0.0159	0.9102
0.050	0.4452	0.9973	0.7872	0.8534	0.4452	0.9973
0.100	0.9232	1.0000	0.9729	0.9936	0.9232	1.0000
0.150	0.9847	1.0000	0.9892	0.9995	0.9847	1.0000
0.200	NC	NC	NC	NC	0.9917 <sup>b</sup>	1.0000 <sup>b</sup>

$L_s(6)$ : 5<sup>th</sup> percentile of beta distribution with  $v_s$  and  $w_s$  shape parameters (Equation 6);  $U_s(7)$ : 95<sup>th</sup> percentile of beta distribution with  $v_s$  and  $w_s$  shape parameters (Equation 7);  $L_h(8)$ : 5<sup>th</sup> percentile of beta distribution with  $v_h$  and  $w_h$  shape parameters (Equation 8);  $U_h(9)$ : 95<sup>th</sup> percentile of beta distribution with  $v_h$  and  $w_h$  shape parameters (Equation 9); **Lowerlimit(10)**: Lower limit of prediction interval for probability of detection when the method is applied in a laboratory (Equation 10); **Upperlimit(10)**: Upper limit of prediction interval for probability of detection when the method is applied in a laboratory (Equation 11); **b**: these values were calculated using Equation 10b and 11b. **NC**: Not calculated.

**Table 5: Results produced during the collaborative trial of a method for the detection of peanut protein in cookies**

Concentration (mg/kg)	Positive responses out of 5	Number of laboratories
0	0	16
0	1	2
1.5	0	17
1.5	1	1
4	0	15
4	1	3
8.2	0	6
8.2	1	5
8.2	2	4
8.2	3	2
8.2	4	1
14	1	3
14	2	2
14	3	2
14	4	4
14	5	7
21	4	2
21	5	16
30	5	18

**Table 6: Estimates of statistical parameters used to describe performance of a method to detect peanut protein in cookies**

Concentration (mg/kg)	$N$	$X$	$\bar{p}(1)$	$s_R$	$v_s(2)$	$w_s(3)$	$v_h(4)$	$w_h(5)$
0	90	2	0.0222	0.0647	0.0932	4.101	2.5	88.5
1.5	90	1	0.0111	0.0471	0.0438	3.901	1.5	89.5
4	90	3	0.0333	0.0767	0.1493	4.329	3.5	87.5
8.2	90	23	0.2556	0.2455	0.5512	1.606	23.5	67.5
14	90	64	0.7111	0.3085	0.8240	0.3347	64.5	26.5
21	90	88	0.9778	0.0647	4.101	0.0932	88.5	2.5
30	90	90	1.0000	0.0000	NC	NC	90.5	0.5

$N$ : Total number of analyses,  $X$ : total number of positive results;  $\bar{p}(1)$ : estimated mean probability of detection (Equation 1);  $s$ : standard deviation of estimates of probability of detection from the individual laboratories;  $v_s(2)$ : shape parameter of beta distribution based on mean and standard deviation of probability of detection (Equation 2);  $w_s(3)$ : shape parameter of beta distribution based on mean and standard deviation of probability of detection (Equation 3);  $v_h(4)$ : shape parameter of beta distribution based on  $N$  and  $X$  (Equation 4),  $w_h(5)$ : shape parameter of beta distribution based on  $N$  and  $X$  (Equation 5). **NC**: Not calculated.

**Table 7: Estimates lower (95%) and upper (5%) limits for the probability of detection in a laboratory using the method to detect peanut protein in cookies**

Concentration (% mg/kg)	$L_s(6)$	$U_s(7)$	$L_h(8)$	$U_h(9)$	Lowerlimit (10)	Upperlimit (11)
0	1.8E-15	0.1376	0.00640	0.0601	1.8E-15	0.0323
1.5	<7E-28	0.0622	0.00196	0.0426	<7E-28	0.5588
4	3.1E-10	0.1892	0.01214	0.0762	3.1E-10	0.9102
8.2	0.00252	0.7617	0.1863	0.3363	0.00252	0.9973
14	0.0848	0.9998	0.6283	0.7841	0.0848	1.0000
21	0.8624	1.0000	0.9398	0.9936	0.8624	1.0000
30	NC	NC	NC	NC	0.9673 <sup>b</sup>	1.0000 <sup>b</sup>

$L_s(6)$ : 5<sup>th</sup> percentile of beta distribution with  $v_s$  and  $w_s$  shape parameters (Equation 6);  $U_s(7)$ : 95<sup>th</sup> percentile of beta distribution with  $v_s$  and  $w_s$  shape parameters (Equation 7);  $L_h(8)$ : 5<sup>th</sup> percentile of beta distribution with  $v_h$  and  $w_h$  shape parameters (Equation 8);  $U_h(9)$ : 95<sup>th</sup> percentile of beta distribution with  $v_h$  and  $w_h$  shape parameters (Equation 9); **Lowerlimit(10)**: Lower limit of prediction interval for probability of detection when the method is applied in a laboratory (Equation 10); **Upperlimit(10)**: Upper limit of prediction interval for probability of detection when the method is applied in a laboratory (Equation 11); **b**: these values were calculated using Equation 10b and 11b. **NC**: Not calculated.

**Table 8: Results produced during the collaborative trial of a method for the detection of salmonella in ground beef**

Concentration (cfu/25g)	Positive responses out of 6	Number of laboratories
0	0	10
0.75	1	1
0.75	2	4
0.75	3	2
0.75	4	2
0.75	5	1
10.75	4	1
10.75	5	2
10.75	6	7

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**Table 9: Estimates of statistical parameters used to describe performance of a method to detect salmonella in ground beef**

Concentration (cfu/25g)	$N$	$X$	$\bar{p}(1)$	$s_R$	$v_s(2)$	$w_s(3)$	$v_h(4)$	$w_h(5)$
0	60	0	0.0000	0.0000	NC	NC	0.5	60.5
0.75	60	28	0.4667	0.2049	2.300	2.63	28.5	32.5
10.75	60	56	0.9333	0.1165	3.343	0.2388	56.5	4.5

$N$ : Total number of analyses,  $X$ : total number of positive results;  $\bar{p}(1)$ : estimated mean probability of

detection (Equation 1);  $s$ : standard deviation of estimates of probability of detection from the individual laboratories;  $v_s(2)$ : shape parameter of beta distribution based on mean and standard deviation of probability of detection (Equation 2);  $w_s(3)$ : shape parameter of beta distribution based on mean and standard deviation of probability of detection (Equation 3);  $v_h(4)$ : shape parameter of beta distribution based on  $N$  and  $X$  (Equation 4),  $w_h(5)$ : shape parameter of beta distribution based on  $N$  and  $X$  (Equation 5).

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**Table 10: Estimates lower (95%) and upper (5%) limits for the probability of detection in a laboratory using the method to detect salmonella in ground beef**

Concentration (cfu/25g)	$L_s(6)$	$U_s(7)$	$L_h(8)$	$U_h(9)$	Lowerlimit (10)	Upperlimit (11)
0	NC	NC	NC	NC	0 <sup>c</sup>	0.0487 <sup>c</sup>
0.75	0.1392	0.8107	0.3635	0.5722	0.1392	0.5588
10.75	0.6756	1.0000	0.8648	0.9719	0.6756	1.0000

$L_s(6)$ : 5<sup>th</sup> percentile of beta distribution with  $v_s$  and  $w_s$  shape parameters (Equation 6);  $U_s(6)$ : 95<sup>th</sup> percentile of beta distribution with  $v_s$  and  $w_s$  shape parameters (Equation 7);  $L_h(8)$ : 5<sup>th</sup> percentile of beta distribution with  $v_h$  and  $w_h$  shape parameters (Equation 8);  $U_h(9)$ : 95<sup>th</sup> percentile of beta distribution with  $v_h$  and  $w_h$  shape parameters (Equation 9); **Lowerlimit(10)**: Lower limit of prediction interval for probability of detection when the method is applied in a laboratory (Equation 10); **Upperlimit(10)**: Upper limit of prediction interval for probability of detection when the method is applied in a laboratory (Equation 11); **c**: these values were calculated using Equation 10c and 11c

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**Table 11: Results produced by a fictional study using the minimum design**

Method	Concentration mg/kg	Number of positive results out of 6	Number of laboratories
A	0	0	10
A	1	6	10
B	0	6	9
B	1	5	2
B	1	6	8

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**Table 12: Estimates of statistical parameters used to describe performance of fictional method A**

Concentration (mg/kg)	$N$	$X$	$\bar{p}(1)$	$s_R$	$v_s(2)$	$w_s(3)$	$v_h(4)$	$w_h(5)$
0	60	0	0.0000	0.0000	NC	NC	0.5	60.5
1	60	60	1.0000	0.0000	NC	NC	60.5	0.5

$N$ : Total number of analyses,  $X$ : total number of positive results;  $\bar{p}(1)$ : estimated mean probability of

detection (Equation 1);  $s$ : standard deviation of estimates of probability of detection from the individual laboratories;  $v_s(2)$ : shape parameter of beta distribution based on mean and standard deviation of probability of detection (Equation 2);  $w_s(3)$ : shape parameter of beta distribution based on mean and standard deviation of probability of detection (Equation 3);  $v_h(4)$ : shape parameter of beta distribution based on  $N$  and  $X$  (Equation 4),  $w_h(5)$ : shape parameter of beta distribution based on  $N$  and  $X$  (Equation 5).

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**Table 13: Estimates lower (95%) and upper (5%) limits for the probability of detection in a laboratory using fictional method A**

Concentration (mg/kg)	$L_s(6)$	$U_s(7)$	$L_h(8)$	$U_h(9)$	Lowerlimit (10)	Upperlimit (11)
0	NC	NC	NC	NC	0.0000 <sup>c</sup>	0.0487 <sup>c</sup>
1	NC	NC	NC	NC	0.9513 <sup>b</sup>	1.0000 <sup>b</sup>

$L_s(6)$ : 5<sup>th</sup> percentile of beta distribution with  $v_s$  and  $w_s$  shape parameters (Equation 6);  $U_s(6)$ : 95<sup>th</sup> percentile of beta distribution with  $v_s$  and  $w_s$  shape parameters (Equation 7);  $L_h(8)$ : 5<sup>th</sup> percentile of beta distribution with  $v_h$  and  $w_h$  shape parameters (Equation 8);  $U_h(9)$ : 95<sup>th</sup> percentile of beta distribution with  $v_h$  and  $w_h$  shape parameters (Equation 9); **Lowerlimit(10)**: Lower limit of prediction interval for probability of detection when the method is applied in a laboratory (Equation 10); **Upperlimit(10)**: Upper limit of prediction interval for probability of detection when the method is applied in a laboratory (Equation 11); **b**: these values were calculated using Equation 10b and 11b, **c**: these values were calculated using Equation 10c and 11c

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**Table 14: Estimates of statistical parameters used to describe performance of fictional method B**

Concentration (mg/kg)	$N$	$X$	$\bar{p}(I)$	$s_R$	$v_s(2)$	$w_s(3)$	$v_h(4)$	$w_h(5)$
0	54	0	0.0000	0.0000	NC	NC	0.5	54.5
1	60	58	0.9667	0.0703	5.341	0.1842	58.5	2.5

$N$ : Total number of analyses,  $X$ : total number of positive results;  $\bar{p}(I)$ : estimated mean probability of

detection (Equation 1);  $s$ : standard deviation of estimates of probability of detection;  $v_s(2)$ : shape parameter of beta distribution based on mean and standard deviation of probability of detection (Equation 2);  $w_s(3)$ : shape parameter of beta distribution based on mean and standard deviation of probability of detection (Equation 3);  $v_h(4)$ : shape parameter of beta distribution based on  $N$  and  $X$  (Equation 4),  $w_h(5)$ : shape parameter of beta distribution based on  $N$  and  $X$  (Equation 5).

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**Table 15: Estimates lower (95%) and upper (5%) limits for the probability of detection in a laboratory using fictional method B**

Concentration (mg/kg)	$L_s(6)$	$U_s(7)$	$L_h(8)$	$U_h(9)$	Lowerlimit (10)	Upperlimit (11)
0	NC	NC	NC	NC	0.0000 <sup>c</sup>	0.0540 <sup>c</sup>
1	0.8222	1.0000	0.9108	0.9904	0.8222	1.0000

$L_s(6)$ : 5<sup>th</sup> percentile of beta distribution with  $v_s$  and  $w_s$  shape parameters (Equation 6);  $U_s(7)$ : 95<sup>th</sup> percentile of beta distribution with  $v_s$  and  $w_s$  shape parameters (Equation 7);  $L_h(8)$ : 5<sup>th</sup> percentile of beta distribution with  $v_h$  and  $w_h$  shape parameters (Equation 8);  $U_h(9)$ : 95<sup>th</sup> percentile of beta distribution with  $v_h$  and  $w_h$  shape parameters (Equation 9); **Lowerlimit(10)**: Lower limit of prediction interval for probability of detection when the method is applied in a laboratory (Equation 10); **Upperlimit(10)**: Upper limit of prediction interval for probability of detection when the method is applied in a laboratory (Equation 11); **c**: these values were calculated using Equation 10c and 11c

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**Table 16: Scenarios used to assess the performance of the draft protocol**

Average probability of positive across laboratories	Expected probability of positive at 95 <sup>th</sup> percentile of laboratories	Beta distribution parameter 'v'	Beta distribution parameter 'w'
0.1	0.2	3.087	27.79
0.05	0.1	3.326	63.2
0.01	0.02	3.518	348.0

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