Risk Assessment for *Cronobacter sakazakii* in Powdered Infant Formula

Report from the risk assessment tool available at www.mramodels.org/esak

Disclaimer

Parameters Entered by the User

Powder contamination parameters

Mean Log Concentration (log_{10} CFU/g):	-3.64
Between Lot Standard Deviation (log_{10} CFU/g)	0.8
Within Lot Standard Deviation (log_{10} CFU/g)	0.8

Sampling Plans

Plan Name	Number of Samples	Sample Mass (g)
No plan	0	0

Reconstitution Temperatures : 70°C, 60°C, 50°C, 40°C, 20°C

Preparation and Handling Scenarios

Method	Stage	Temperature (C)	Duration (h)	Holding Conditions
Preparation Scenario - 6h	Preparation of formula	20	0.2	Still Air and Bottle

storage in refrigerator				
	Holding/Cooling	6	6	Still Air and Bottle
	Active re-warming/ rapid cooling	37	0.2	N/A
	Feeding Period	20	2	Still Air and Bottle
Preparation Senario - 12h storage in refrigerator	Preparation of formula	20	0.2	Still Air and Bottle
	Holding/Cooling	6	12	Still Air and Bottle
	Active re-warming/ rapid cooling	37	0.2	N/A
	Feeding Period	20	2	Still Air and Bottle
Preparation Senario - 24h storage in refrigerator	Preparation of formula	20	0.2	Still Air and Bottle
	Holding/Cooling	6	24	Still Air and Bottle
	Active re-warming/ rapid cooling	37	0.2	N/A
	Feeding Period	20	2	Still Air and Bottle
Preparation Senario - 48h storage in refrigerator	Preparation of formula	20	0.2	Still Air and Bottle
	Holding/Cooling	6	48	Still Air and Bottle
	Active re-warming/ rapid cooling	37	0.2	N/A
	Feeding Period	20	2	Still Air and Bottle

Key Assumptions

- It is assumed that the level of contamination is sufficiently low that contamination occurs at a level of 1 CFU per serving prior to rehydration.
- It is assumed in this model that all lots of PIF would be tested against the microbiological criteria and lots deemed unacceptable given the criteria are removed from the supply. If a lesser degree of testing was undertaken (e.g. only every other lot tested), the ability of the testing program to remove unacceptable lots would decrease proportionally.
- It is assumed that the concentration of *C. sakazakii* both between and within lots of PIF can be described by a lognormal distribution, or equivalently the log concentration follows a normal distribution.

Results

These results are based upon the values entered into the tool by the user as listed above.

Sampling Plans

No sampling plans were entered.

Risk Factor Reduction by Scenario

This table presents the relative risk reduction associated with each combination of reconstitution temperature, preparation method, and sampling plan. The relative risk reduction is the risk reduction compared to the selected baseline combination. The baseline is highlighted in the table.

Reconstitution Temperature (C)	Preparation Method	Sampling Plan	Relative Risk Reduction (compared to the selected baseline*)
50	Preparation Senario - 48h storage in refrigerator	No plan	0.30
50	Preparation Senario - 24h storage in refrigerator	No plan	0.67
50	Preparation Scenario - 6h storage in refrigerator	No plan	1.00
50	Preparation Senario - 12h storage in refrigerator	No plan	1.47
60	Preparation Senario - 48h storage in refrigerator	No plan	1.56
40	Preparation Senario - 48h storage in refrigerator	No plan	1.93
40	Preparation Senario - 24h storage in refrigerator	No plan	2.96
60	Preparation Senario - 24h storage in refrigerator	No plan	3.54
40	Preparation Scenario - 6h storage in refrigerator	No plan	4.43
60	Preparation Scenario - 6h storage in refrigerator	No plan	5.33
60	Preparation Senario - 12h storage in refrigerator	No plan	6.28
40	Preparation Senario - 12h storage in refrigerator	No plan	7.08
20	Preparation Senario - 48h storage in refrigerator	No plan	14.76
20	Preparation Senario - 24h storage in	No plan	29.71

	refrigerator		
20	Preparation Scenario - 6h storage in refrigerator	No plan	43.20
20	Preparation Senario - 12h storage in refrigerator	No plan	43.20
70	Preparation Senario - 48h storage in refrigerator	No plan	> 1.00E+5
70	Preparation Senario - 24h storage in refrigerator	No plan	> 1.00E+5
70	Preparation Scenario - 6h storage in refrigerator	No plan	> 1.00E+5
70	Preparation Senario - 12h storage in refrigerator	No plan	> 1.00E+5