

Risk Assessment for *Cronobacter sakazakii* in Powdered Infant Formula

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

Disclaimer

All reasonable precautions have been taken by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) in creating this risk assessment tool and the documentation accompanying it. However, the Food and Agriculture Organization of the United Nations and the World Health Organization decline all responsibility for errors, omissions or deficiencies regarding the risk assessment tool and the accompanying documentation. FAO and WHO also decline all responsibility for program maintenance and for updating and upgrading the risk assessment tool or the accompanying documentation. The risk assessment tool and the accompanying documentation are being made available without warranty of any kind, either expressed or implied. Responsibility for the interpretation and use of the risk assessment tool and of the accompanying documentation lies solely with the user and/or the reader. In no event shall FAO or WHO be liable for damages arising from their use.

The designations employed and the presentation of material in this information product do not imply the expression of any opinion whatsoever on the part of the World Health Organization nor of the Food and Agriculture Organization of the United Nations concerning the legal or development status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

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

<u>Plan Name</u>	<u>Number of Samples</u>	<u>Sample Mass (g)</u>
No plan	0	0

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

Preparation and Handling Scenarios

<u>Method</u>	<u>Stage</u>	<u>Temperature (C)</u>	<u>Duration (h)</u>	<u>Holding Conditions</u>
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
Preparation Senario - 24h storage in refrigerator	Feeding Period	20	2	Still Air and Bottle
	Preparation of formula	20	0.2	Still Air and Bottle
	Holding/Cooling	6	24	Still Air and Bottle
Preparation Senario - 48h storage in refrigerator	Active re-warming/ rapid cooling	37	0.2	N/A
	Feeding Period	20	2	Still Air and Bottle
	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