

Sanitation Standard for the Microorganism in Infant Foods

Article 1

This Standard is prescribed in accordance with the provisions of Article 17 of the Act Governing Food Safety and Sanitation.

Article 2

This standard applies to powdered or liquid formula for infants not more than 12 months of age, intended to supplement breast milk, and the follow-up infant formula manufactured primarily from the edible components of cereals and legumes which should constitute at least 25% of the final mixture on a dry weight basis.

Article 3

The maximum level of microorganism for infant foods:

Microorganisms	Sampling plan ⁽¹⁾		Limits ⁽²⁾		Remark
	n	c	m	M	
<i>Coliform</i> (MPN/g)	5	2	$<3^{(3)}$	10	The detected results allowable between m and M from $\leq c$ sample quantity. Unacceptable $\geq M$.
<i>Enterobacter sakazakii</i> (<i>Cronobacter</i> species)	10	0	0	negative	Apply to powdered infant formula.
<i>Salmonella</i> spp.	10	0	0	negative	
<i>Listeria monocytogenes</i>	10	0	0	negative	
⁽¹⁾ n = number of units comprising the sample. c = maximum allowable number of sample units yielding results between m and M (marginally acceptable). ⁽²⁾ m = a microbiological limit that separates good quality from marginally acceptable quality. M = a microbiological limit above which sampling results are unacceptable or defective. ⁽³⁾ m = “ <3 ” is the MPNs per gram that refer to the methods of test for Coliform bacteria .					

Article 4

This Standard shall be implemented at release date.