

# Draft Standards for Sanitation and Pesticide Residue Limits in Infant Foods

## Article 1

This Standard is prescribed in accordance with the provisions of Article 17 and the second paragraph of Article 15 of the Act Governing Food Safety and Sanitation (herein referred to as "this Act").

## Article 2

This standard applies to powdered or liquid formula for infants below 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 infant foods shall have their original pleasant flavor and color. No putridity, discoloration, off odor or flavor, contamination, moulds, foreign matter or parasite shall be found.

## Article 4

The maximum level of microorganism:

Microorganisms	Sampling plan <sup>(1)</sup>		Limits <sup>(2)</sup>		Remark
	n	c	m	M	
<i>Coliform</i> (MPN/g)	5	2	<sup>(3)</sup> < 3	10	The detected results allowable between m and M from $\leq c$ sample quantity. Unacceptable $\geq M$ .
<i>Enterobacter sakazakii</i> ( <i>Cronobacter species</i> )	10	0	0	-	Apply to powdered infant formula.
<i>Salmonella</i> spp.	10	0	0	-	
<i>Listeria monocytogenes</i>	10	0	0	-	
<sup>(1)</sup> n = number of units comprising the sample. c = maximum allowable number of sample units yielding results between m and M (marginally acceptable). <sup>(2)</sup> 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 5

The tolerance of mycotoxins in infant foods:

<b>Mycotoxins</b>	<b>Food category</b>	<b>Limit (ppb)</b>
Aflatoxin B1	Processed cereal-based foods	0.1
Aflatoxin M1	infant milk	0.025
Ochratoxin A	Processed cereal-based foods	0.50
Zearalenone	Processed cereal-based foods	20
Deoxynivalenol	Processed cereal-based foods	200
Fumonisin B1+B2	Processed maize-based foods	200

Article 6

The tolerance of heavy metal in infant foods:

<b>Heavy metal</b>	<b>Limit (ppm)</b>
Lead	0.02
Tin	50 (Canned foods)

Article 7

The infant foods residue pesticide shall not be more than 0.01 ppm.

(This limit is reference to pesticides minimum detectable level.)

Violation of the preceding provisions, punished accordance with subparagraphs 5 of paragraph 1 of Article 15 of this Act.

Article 8

In addition to the provisions of the preceding Article, violation of this standard punished accordance with Article 17 of this Act.

Article 9

This Standard shall be implemented from the date of promulgation.