

**DRAFT AMENDMENT OF REGULATION 26A AND TWELFTH SCHEDULE, FOOD  
REGULATIONS 1985  
(Probiotic Cultures)**

1) Draft Amendment of Regulation 26A

Malaysia proposes to amend Regulation 26A by substituting the existing requirements for bifido bacteria with a new standard for probiotic cultures permitted to be added to food as follows:

- i) Probiotic culture means live microorganisms which when administered in adequate numbers confer health benefits on the host;
- ii) Probiotic culture shall comply with the following criteria:
  - has been evaluated for its safety to human and beneficial to health as demonstrated in human studies;
  - resistant to gastric acidity;
  - resistant to bile acid;
  - adhere to mucus and/or human epithelial cells and cell line;
  - able to hydrolyse bile salts;
  - has a long history of consumption; and
  - has clear taxonomy identification (genus, species, strain)
- iii) Probiotic cultures added shall remain viable and the viable count shall not be less than  $10^6$  cfu / ml or cfu / g during the shelf life of the product
- iv) Probiotic cultures shall not contain antibiotic resistant genes
- v) The following information should be clearly labelled on package of food which probiotic cultures have been added:
  - a) the words “contain at least  $10^6$  cfu/ml or cfu/g of probiotic cultures”;
  - b) the genus, species and strain designation of the probiotic cultures; and
  - c) the direction for storage before and after package has been opened.
- vi) Where the media used for propagation and maintenance of the probiotic cultures are derived from animal, the common name of such animal shall be stated on the label in the following form:

“Media used for propagation of probiotic cultures derived from (the common name of such animal)
- vii) The following claim may be added to the label of food to which probiotic cultures have been added:

“Probiotic cultures help in improving intestinal/or gut function” or in any other words of similar meaning

2) Draft Amendment of the Twelfth A Schedule

The Twelfth Schedule is amended by replacing the existing schedule with a new proposed schedule for Probiotic Cultures as follows:

<b>Twelfth A Schedule (Existing)</b>	<b>Twelfth A Schedule (Proposed Amendment)</b>
<b>1. <i>Bifidobacterium</i> sp.</b> <i>Synonyms: "Tissieria", "Bifidibacterium"</i>	
-	<i>B. bifidum</i> Bb-02
-	<i>B. breve</i> strain Yakult
Bifido bacterium lactis (L-form)	<i>B. lactis</i> BB-12
	<i>B. lactis</i> HN019 (BBi™, DR10™, Howaru)
	<i>B. lactis</i> BI-04
	<i>B. lactis</i> Bi-07
	<i>B. lactis</i> Bif.420
Bifido bacterium longum (L-form)	<i>B. longum</i> BB536 ( <i>B.longum</i> NCC 3001)
	<i>B. longum</i> BB-46
	<i>B. longum</i> Rosell-175
<b>2. <i>Lactobacillus</i> sp.</b>	
-	<i>L. acidophilus</i> LA-5
-	<i>L. acidophilus</i> Howaru™ Dophilus NCFM
-	<i>L. acidophilus</i> La-14
-	<i>L. acidophilus</i> Rosell-52
-	<i>L. casei</i> Shirota
-	<i>L. johnsonii</i> La 1/Lj 1 ( <i>L.johnsonii</i> NCC533)
-	<i>L. paracasei</i> 01
-	<i>L. paracasei</i> 431
-	<i>L. paracasei</i> Lpc-37
-	<i>L. paracasei</i> NCC 2461 (ST11)
-	<i>L. plantarum</i> Lp-115
-	<i>L. rhamnosus</i> (ATCC 53103)
-	<i>L. rhamnosus</i> Lr-32
-	<i>L. rhamnosus</i> HN001 (DR20™, <i>L. rhamnosus</i> Howaru)
-	<i>L. rhamnosus</i> Rosell-11
-	<i>L. salivarius</i> Ls-33