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Morinaga Milk Obtains the Registration of "New Food Ingredient" in China for use of its Probiotic *Bifidobacterium longum* BB536 in Infant and Toddler Foods

Morinaga Milk Industry Co., Ltd. announced its proprietary probiotic *Bifidobacterium longum* **BB536** was approved by the National Health Commission (NHC) of the People’s Republic of China as a new food ingredient for use in infant and toddler foods (under the age of three) on 11th May 2022.

Following a complex and lengthy registration process, the probiotic strain *B. longum* BB536 meets the highest standards of safety and regulatory compliance and has now completed the approval process for use as an ingredient in infant and toddler milk and food products for children under three years old in China.

“We are extremely proud to have achieved the registration process and consider it an endorsement of the core values of Morinaga Milk’s HRB (human-residential bifidobacteria),” said Dr. Xiao, General Manager of Next Generation Science Institute of Morinaga Milk. “We believe the highest safety standards that we uphold and the strong scientific evidence behind BB536 are what brought us come this far. It has been a long registration process and this approval is an incredible regulatory achievement given the limited number of strains that made it to the list of only 14 strains, including BB536,” he added.

Stringent safety requirements

The “New Food Ingredient” is a regulatory system required for food ingredients to be specifically permitted to use in general foods and infant and toddler foods (<3 years) in China. The registered ingredient must meet certain requirements in terms of nutrition, health, and safety and comply with the regulatory standards in China. To date, there are only 13 registered probiotic strains that can be used in infant and toddler foods in China (six strains in 2011, three in 2016, three in 2020, and one in 2021). The company’s flagship strain, *B. longum* BB536, is a new addition to the positive list.

Morinaga Milk is the only Japanese company to have obtained the registration for probiotic strains. *B. longum* BB536 is the company’s second strain to have obtained the approval, following *B. breve* M-16V in 2016. The company focuses on human-residential bifidobacteria (HRB) – the natural inhabitants of the human gut that exhibit numerous superior physiological functions. Morinaga Milk is committed to develop high quality, safe, reliable and natural probiotics over the past decades and is some way ahead of the curve in HRB research. Both BB536 and M-16V approved by the China’s NHC are the HRB strains.

“The registration process is hard and it should be because the ingredient is dedicated for a vulnerable population. There were some changes in the regulatory frameworks and the safety requirements has become more stringent,” said Dr. Xiao. “However, along with an exceptionally long history of safe use in humans, including infants and young children, the safety and efficacy of BB536 continues to be undoubtedly proven through solid science, leading to the acknowledgement by the China’s NHC,” he added.

All set for use in infant and toddler milk

The Chinese infant and toddler milk market has tripled in size in the 10 years between 2010 and 2019, and is expected to be worth \$24.4 billion in 2020, accounting for 47% of the global market (Euromonitor International "Milk Formula in China", September 2021). In addition, the market for infant and toddler milk containing the probiotics *Bifidobacterium* strain has been on the rise in recent years (Research by Morinaga Milk Industry Co., Ltd. using Mintel GNPD, November 2021).

Under the Morinaga Milk Group's 10-Year Vision, the company aims to achieve a global business sales ratio of 15% or more by the fiscal year ending March 2029. The company is eyeing the giant infant and toddler milk market in China and aim to strengthen its sales in China to help achieve the goal.

Morinaga Milk's *B. longum* BB536 has received the FDA GRAS notification in US for use in conventional foods (GRAS Notice No. GRN 000268) and infant and toddler milk (GRAS Notice No. GRN 000877). It has been incorporated in various products worldwide for more than 50 years. Affirmation of this newest registration in China adds value to the company's proprietary probiotic strain, diversifying its application options available in the infant category.

First *B. longum* subsp. *longum* strain in the approval list

Bifidobacterium longum BB536 is a clinically effective, well-established, multifunctional probiotic strain that has a long history of human use (supported by more than 220 scientific studies (as of March 2022)). For half a century, *B. longum* BB536 has been the superior Human-Residential Bifidobacteria (HRB) probiotic strain that provides a consistent beneficial effect in maintaining human health. Already well known as a leading functional probiotic ingredient for application in food and dietary supplements, Morinaga Milk's *B. longum* BB536 is now expanding its application opportunities into the new space, to be specifically permitted for use in infant and toddler milk and foods in China.

“We have always been researching on bifidobacteria, particularly those that naturally occur in the human gut, which are known as the HRB strains,” Dr. Fumiaki Abe, Director of Research and Development Institute of Morinaga Milk. “We obtained the approval for our first HRB strain, *B. breve* M-16V in 2016, and we are extremely delighted that BB536 have now also passed the stringent process to obtain the Chinese approval pertaining to infant and toddler foods.” “BB536 is the first *B. longum* subsp. *longum* strain of HRB in the positive list and its potential is very much exciting,” he added.

Pioneering in bifidobacteria research

Morinaga Milk Industry Co., Ltd. is one of the leading dairy product companies in Japan with a century of history harnessing the nutritional properties of dairy products and its functional ingredients. Morinaga Milk is also a key global probiotics manufacturer that excels in innovative technology and offers a premium line of probiotics and functional ingredients worldwide. Since the 1960s, Morinaga Milk has been engaged in research on the safety, functional health benefits, and mechanisms of action of probiotic bifidobacteria to better understand their role in maintaining human health. For more information about Morinaga Human-Residential Bifidobacteria (HRB) probiotics, please visit us at <https://morinagamilk-ingredients.com/>.