Letter to the Editor

A Subchronic Toxicity Study on *Lactobacillus Fermentum* GM 090 in Rat*

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Lactobacillus fermentum (*L. fermentum*) is one of seven species in the genus *Lactobacillus*[1]. With a long history of safe use in fermented food production, *Lactobacillus* is considered as one of the most beneficial probiotics[2-3]. The most well-known potential health benefit is improving digestion and immune function[4-5]. Other beneficial functions of *Lactobacillus* strains include managing lactose intolerance[5], lowering cholesterol and blood pressure[5], reducing inflammation[6], and prevention of cancer[5,7]. *L. fermentum* is usually found during malt whisky fermentation[8]. *L. fermentum* CP34 was found to have the significant effect of decreasing the serum antigen-specific IgE levels compared to a control group[9].

In recent years, many new *Lactobacillus* strains with probiotic attributes are being introduced into food products due to the growing consumer awareness concerning diet and health. For traditional *Lactobacillus* strains, they have an excellent history of safe use in the formation of dairy products and other foods and some have "generally recognized as safe" (GRAS) status[10], however, newly isolated organisms often have no previous history of food product use, thus, they do not necessarily share the GRAS status of traditional Lactobacillus strains. Therefore, it is necessary and essential to conduct the safety assessment on any new strain with the intent to be added into foods or used as a dietary supplement. We have conducted a 90-day feeding study on a new strain of *L. paracasei* in our lab and the results confirmed that no subchronic toxicity was observed[11]. *L. fermentum* GM 090 has the similar morphological characteristics like rod-like shape with round edge with *L. paracasei* GM 080, and both of them belong to the the genus Lactobacillus. However, they have obvious difference: *L. paracasei* GM 080 is a strain of *L. paracasei*, and *L. fermentum* 090 is one of strains of *L. fermentum*. Yeung et al.[12] analyzed the 16s rDNA sequence and randomly amplified polymorphic DNA (RAPD analysis) of this strain. The result found that GM 090 belongs to *Lactobacillus fermentum*, but has a specific RAPD patterns. Given this, GM 090 is a novel *Lactobacillus fermentum* strain. Therefore, the present study aims to evaluate the subchronic toxicity of *L. fermentum* GM 090 when administered daily by gavage to Sprague Dawley rats for 90 days.

Groups of 10 male and 10 female weaning Sprague-Dawley rats were given 0, 1.25, 2.5, and 5.0 g/kg body weight *Lactobacillus fermentum* GM 090 by gavage, respectively. Clinical observations were recorded daily. Body weights and food consumption were measured weekly. Blood samples were obtained in the middle of the study (day 46) and at the end of the study for measurement of hematology and clinical chemistry. At the end of the study, all animals were euthanized for necropsy. Selected organs were weighted and recorded. Histological examination was performed on all tissues from animals in the control and high dose groups. The study was conducted at the National Institute for Nutrition and Food Safety (Beijing, China) in compliance with the Food and Drug Administration (FDA) principles of GLP and in accordance with the FDA Guidance for Industry and Other Stakeholders, "Toxicological Principles for the Safety Assessment of Food Ingredients Redbook 2000-Subchronic Toxicity Studies with Rodents"[13]. This protocol has been approved by the Office of Laboratory Animal Welfare, National Institute for Nutrition and Food Safety.

L. fermentum GM 090 (Lot No. 20070618001), a brown powder, provided by GenMont Biotech Incoporation (Taiwan, China) and stored at 2-8 °C in a refrigerator, was used in this study. The concentration of the tested bacteria is $\geq 2\times10^9$ cfu/g. The viability was tested throughout the study, and the *L. fermentum* GM 090 counts on Day 0, Day 30, Day 60, and Day 90 were constant ($\geq 2\times10^9$ cfu/g), which confirmed that the bacteria were alive during the study.

Sprague-Dawley rats were received from Vital River Laboratory Animal Technology Co, Ltd (Beijing, China). All animals were examined for clinical signs of

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