

Nonclinical Safety Assessment of Probiotics: Global Regulations and Yakult's Approach

Masao Togao¹,

Safety Research Department, Yakult Central Institute, Kunitachi/Tokyo, Japan

Abstract

Probiotics are defined as “live microorganisms that, when administered in adequate amounts, confer a health benefit on the host.” With growing awareness of health promotion and disease prevention, the consumption of probiotics has become increasingly widespread. Furthermore, probiotics are consumed not only by healthy individuals but also by potentially vulnerable populations, including patients, infants, and older adults. Accordingly, it is important to ensure the safety of probiotics for individuals of various ages and medical conditions.

Comprehensive regulatory frameworks have been established in the United States (U.S.) and Europe to ensure the safety of novel foods and ingredients, including probiotics. In the United States, such products may be evaluated under the Generally Recognized as Safe (GRAS) or New Dietary Ingredient (NDI) frameworks, while in the European Union (EU), they may be evaluated under the Novel Food (NF) regulation. In addition, the European Food Safety Authority (EFSA), which evaluates NF applications, has established the Qualified Presumption of Safety (QPS) system for microorganisms intended for use as food or food ingredients. In Japan, unlike the U.S. GRAS and NDI frameworks or the EU QPS system, no comprehensive safety evaluation system has been established for probiotic strains. Instead, safety assessments are primarily conducted in accordance with the regulatory framework applicable to specific food categories, such as Foods with Function Claims (FFC), Foods for Specified Health Uses (FOSHU), and Foods for Special Dietary Uses (FOSDU).

In this presentation, I will provide an overview of the safety assessment criteria required under the regulatory frameworks of the U.S., the EU, and Japan and introduce Yakult's approach to ensuring the safety of probiotics. I hope that this presentation will stimulate discussion among participants regarding the types of tests and evaluations that should be conducted to ensure the safety of probiotic products.

Keywords: *Probiotics, GRAS, NDI, NF, FOSHU*

¹Corresponding author: Masao Togao (E-mail: masao-togao@yakult.co.jp)
Doi: (The Journal will assign a doi number for the published article)