Report

Food Enzyme Global Regulations

Food enzymes are essential to the production of many foods around the globe, including bread, dairy products, Japanese sake, juice, miso, and soy sauce. Enzymes make use of natural processes to stabilize the flavor and texture of foods. They also reduce production time and energy use, lowering environmental impact. As a result, they also contribute to reducing food loss.

Around the world, efforts have been made to establish rules to ensure the safe use of enzymes. The development of international regulations began in the 1970s, with early safety evaluations conducted by UN bodies such as JECFA (the FAO/WHO Joint Expert Committee on Food Additives) and the U.S. Food and Drug Administration, forming the foundation of today's regulatory systems.

In the European Union, all food enzymes are subject to safety evaluation under food enzymes regulations introduced in 2008, with the ongoing registration of such enzymes on a Union List. Applications for registration require detailed data, including full genome information of the production strain and assessments of toxicity and allergens. A highly transparent electronic application system has been established, and discussions on simplifying evaluations are also underway. The Union List is scheduled to come into effect in 2028.

In the United States, enzymes recognized as safe are widely used under the GRAS system. While a fundamental review of the GRAS system is currently under consideration, the FDA is also examining the introduction of new toxicity assessment tools. Under these tools, enzymes are expected to be classified in the lowest toxicity category.

In Japan, many enzymes are treated as existing food additives. In 2025, a notification system for production strains was introduced, further enhancing transparency and safety.

In China, reviews are conducted based on national standards (GB standards). In Australia and New Zealand, FSANZ (Food Standards Australia New Zealand) conducts scientific evaluations, and the review process is made public through a public comment system.

Regulations governing enzymes vary by country and region. Beyond legal requirements, it is also important to understand the cultural and social values that shape these regulatory frameworks and to stay aligned with the latest developments. Enzymes play an important role in helping to address global challenges. Amano Enzyme will continue to adapt to evolving regulations to deliver safe and high-quality enzymes worldwide while safeguarding both food quality and safety.

Regulatory Systems by Country (as of 2025)

Country/Region	Regulatory System	Key Features and Recent Developments
EU	Food Enzymes Regulation (Reg. EC No.1332/2008)	Registration on the Union List after safety evaluation Union List scheduled to take effect in 2028 Electronic application system and discussions on simplified evaluation
United States (USA)	GRAS system	Wide use of enzymes recognized as safe Consideration of abolishing self-affirmed GRAS system Introduction of evaluation tools and response to synthetic biology
Japan	Existing additive system New approval system	Notification system for production strains to be effective in 2025 Enhanced information disclosure
China	National standards (GB standards)	More stringent analytical documentation requirements
Australia/ New Zealand	FSANZ review system	Scientific evaluation, transparency, and public comment system