

January, 2013

***Lactobacillus casei* Strain Shirota Granted GRAS Status****by U. S. Food and Drug Administration (FDA)**

—GRAS status expected to give Yakult a further boost in the U.S. market—

Yakult Honsha Co., Ltd. (President: Takashige Negishi) hereby announces that the company's *Lactobacillus casei* strain Shirota had its safety approved in the food safety review system (GRAS) in the U.S. and attained GRAS (Generally Recognized as Safe) status from the U.S. FDA (GRAS Notice No. 429).

In March 2012, *Lactobacillus casei* strain Shirota obtained self-affirmed GRAS status following a rigorous review by a panel of renowned experts on toxicology, nutrition, and molecular biology. Subsequently, Yakult Honsha notified the FDA of the self-affirmed GRAS status and *Lactobacillus casei* strain Shirota received GRAS status from the FDA. The number of GRAS substances approved by the FDA is limited and the attainment of the status proves *Lactobacillus casei* strain Shirota's topmost safety as food in the U.S.

Set forth by the U.S. FDA, GRAS is a certification system for food safety unique to the United States. Substances affirmed as GRAS are widely recognized, not only in the country but also internationally, as food or food chemical substances that have been certified safe after rigorous review. It is considered desirable for food or food chemical substances for sale to be recognized as GRAS substances.

In 1997, a notification system under which manufacturers notify the FDA of their self-affirmed GRAS declarations was implemented. Manufacturers obtain the self-affirmed GRAS status following documentary examination by an expert panel and submit the documents to the FDA, which would review the substance for approval. Once approved, the substance will be included in the list of GRAS substances and the fact will be widely notified through the FDA's website, etc.

In the United States, Yakult U.S.A. Inc. has been distributing the Yakult fermented milk drink since 1999, and has been enjoying robust sales. The first Yakult production plant in the U.S. is expected to start its operation in 2013.

With the attainment of GRAS status, we aim to raise the awareness regarding the safety of *Lactobacillus casei* strain Shirota and further promote the Yakult fermented milk drink not only in the U.S. but also the rest of the world.