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Basic Approach of the Safety Assessment of Food for Specified Health Uses (FOSHU)

1. Background

The safety and effectiveness of food products submitted for the approval of Food for Specified Health Uses (FOSHU) had been evaluated by the Ministry of Health, Labour and Welfare (MHLW) until June 2003.

After the Food Safety Basic Law was enforced in July 2003, the Food Safety Commission of Japan (hereinafter referred to as the “FSCJ”) has become responsible for conducting the safety assessment of FOSHU in response to a request from the Minister of the MHLW¹. Expert Committee on Novel Foods (hereinafter referred to as “Expert Committee”) established under the FSCJ now conducts science-based safety assessments. The Expert Committee has completed several assessments to date upon request from the MHLW¹. This basic approach was compiled to ensure greater transparency of the safety assessment of FOSHU in the future.

2. Basic Approach

The safety assessment of FOSHU is conducted on a case-by-case basis for individual food products, while, in principle, safety shall be evaluated for the functional components relevant to its specified health use, thoroughly considering the composition of the food, history of safe food use of the products and/or its functional component, and food form types.

In the case where the FOSHU is in a form different from that of conventional food, such as tablets, capsules, extracts and powders, they are likely to be consumed excessively. Therefore, the safety of such FOSHU shall be evaluated thoroughly considering the dosage form, possible intake amount, and other factors.

As for such types of foods, cooking/processing methods and the highest possible intake (amount

¹Jurisdiction of the approval for FOSHU was transferred to the Consumer Affairs Agency in September 2009.