Establishment of the Maximum Limit for Deoxynivalenol (DON) in Foods.

Outline of revision

From the viewpoint of public health, the Minister of Health, Labour and Welfare (MHLW) is authorized to establish specifications and standards for food or additives to be served for the purpose of marketing by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council. (Food Sanitation Act Article 11 Paragraph 1)

Based on the conclusion of discussion conducted by the Committee on Standards for Food* on September 22, 2017, the MHLW has decided to establish a maximum limit (ML) for Deoxynivalenol (DON) in wheat at 1.0 mg/kg.

** The Committee of the Standards for Food is one of the advisory bodies of the Food Sanitation Council that is established under the Pharmaceutical Affairs and Food Sanitation Council.*

Background

Deoxynivalenol (DON) is a trichothecene mycotoxin produced in cereals (especially wheat, maize and barely) by mainly *G. zeae*, *F. graminearum* and *F. culmorum*. It is known to cause acute toxicity characterized by emesis and disorders of the lymphoid tissue and digestive tract and chronic toxicity characterized by symptoms including weight loss.

In May 2002 the MHLW established a provisional standard limit of 1.1 mg/kg for wheat because a high concentration of DON (2.2 mg/kg) was detected in wheat distributed in the Japanese market. In July 2015 the Codex Alimentarius Commission set maximum levels for DON in wheat, maize, and barley. (CODEX STAN 193-1995)

Wheat is a secondary staple food in Japan and most of wheat consumed in Japan is imported. In light of past food poisoning cases associated with DON, Japan will establish the ML for DON in wheat to prevent a public

health risk. The ML has been derived applying the Codex ALARA principle[1], based on the actual situation of contamination of imported wheat and exposure assessment for Japanese consumers.

Provisional standard	Maximum Limit (draft)
1.1 mg/kg for wheat	1.0 mg/kg for wheat

Concept of setting MLs

- Codex Alimentarius Commission separately set the maximum levels for DON in cereals (wheat, maize, and barley) in three categories: cereal grains for further processing, flour, and cereal-based foods for infants and young children. In Japan, however, it is difficult to process wheat to reduce possible contamination by DON. In addition, it is not easy to separately regulate wheat-based foods for infants and children.
- Exposure assessment conducted by the Ministry of Agriculture, Forestry and Fisheries of Japan has found that if a maximum limit (ML) of 1.0 mg/kg is applied to wheat, the 95th percentile of the orally ingested DON by pre-school children would be the same level as the tolerable daily intake (TDI) for DON set by the Food Safety Commission of Japan, a risk assessment body, in the Cabinet Office. This means the application of the ML of 1.0 mg/kg will ensure food safety.
- Codex Alimentarius Commission sets maximum levels as low as reasonably achievable based on actual contamination studies, considering so that the violation rate can be 2–3%. According to the study carried out by the MHLW, an ML of 1.0 mg/kg will result in a violation rate of about 2%.

[1] The ALARA principle: The principle that MLs should be set "As Low As Reasonably Achievable." The principle is used for Codex Committee on Contaminants in Foods to set standards.