Provisional translation

April 23, 2018

Expert Committee on Biotech Foods

This English version of the Expert Committee Decision is intended to be reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The Food Safety Commission of Japan (FSCJ) shall not be responsible for any consequence resulting from use of this English version.

Stance on the Safety Assessment of GM Plants for Food Use

1. Background

1) Applicants are requested to provide information on the DNA insertion into the host plant according to "Standards for Safety Assessment of Genetically Modified Foods (Seed plants) (Food Safety Commission Decision of January 29, 2004)". This should include the structure/copy number of the inserted DNA together with the flanking sequences of each insertion site and shall aim to demonstrate that genetic modification does not cause unintended changes in endogenous genes.

2) Applicants shall also demonstrate that unintended fragments from targeted DNA or vector DNA backbone are not inserted into the host plant, while only the targeted DNA is introduced.

3) In the safety assessment, even if the host plant and inserted genes are identical, each single transformation event (herein after referred to as "event") should be assessed, because the gene of interest may be inserted into a different site of a genome of the host plant during the transgenic process and possibly produce different events.

4) However, in the discussion at the past Expert Committee, it was indicated that in some cases, applicants estimate the above 1) and 2) of the original GM plant for application (not necessarily indicating the T0 transgenic plants) by submitting the analysis results of its progeny generations, and such discussion lead to the development of this Stance.

2. Basic Stance

1) An event-specific assessment should be conducted. A method for identification of a single event should follow 1.-1) and 2). The transgenic/GM plant which exhibit the identical molecular characteristics confirmed by 1.-1) and 2) are considered as one event.

2) In principle, 1.-1) and 2) should be confirmed based on the analysis result of the original GM plant for application. In the case where the GM plant of the analyzed generation is not confirmed to have identical molecular characterization, this analyzed plant should be used for the subsequent conventional breeding.

3) Regardless of the principle 2.-2), when the progeny generation is analyzed, an adequate number of plants should be used and the methods should be sufficiently sensitive to detect variations within the event taking into account polyploidy of the host plant and segregation ratio.

（Reference）