The case for deregulation of Category 1x1 stack

Hiroaki Kodama
Chiba University, Chiba, Japan
e-mail: kodama@faculty.chiba-u.jp

Abstract

In Japan, food safety assessment of genetically modified plants (GM plants) has been conducted from 2004 according to a guideline, "Standards for the safety assessment of genetically modified foods (seed plants)". GM plants produced by conventional breeding between the approved GM plants are so-called "stacked products" and safety assessment of these products is also conducted. After safety assessment of the single-event GM plant is completed, each single GM product is classified into one of the following three categories based on the characteristics of transgene. (1) Category 1 (Cat. 1) is the event in which the transgene has no effects on the host metabolites, and it includes the traits such as herbicide tolerance, insect resistance and virus resistance. (2) Category 2 (Cat. 2) is the event in which the transgene product modifies the host plant metabolism, for instance, the high oleate-producing GM soybean. (3) Category 3 (Cat. 3) is the event in which plant metabolites are used as substrates of the transgene products, and new metabolites that are not found in the host plants are produced. A total of 191 cases of stacked product between Cat. 1 and Cat. 1 were subjected to safety assessment during 2004 to Dec. 2013, and there was no stacked product that showed any changes of the GM traits compared to the parental single-event plant. Thus, the subcommittee of Ministry of Health, Labour and Welfare (MHLW) concluded that there is no additional concern of the Cat. 1 × Cat. 1 stacked product. The review process of the Cat. 1 × Cat. 1 stacked product was revised in June 2014, and safety assessment of these stacked products has been no longer required. Here I introduce the concept of safety assessment of stacked products in Japan and show the process by which we deregulated these products.

Key words: deregulation, food safety assessment, GM plants, stacked products