Stance on Safety Assessments of Additives Produced Using Genetically Modified Microorganisms, whose End Product is a Highly Purified Nonprotein Additive, such as Amino Acids
(Supplementary Provisions of Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms, Food Safety Commission Decision of March 25, 2004)

(Food Safety Commission Decision of April 28, 2005)

In respect of additives produced using genetically modified microorganisms (hereinafter referred to as "Genetically Modified Additives"), based on "Standards for Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms (hereinafter referred to as "Assessment Standards") (Food Safety Commission Decision of March 25, 2004), safety assessment is carried out individually for the additives within the scope of those approved for use by the Food Sanitation Act. Regarding Genetically Modified Additives, the Assessment Standards state that generally speaking it is appropriate to perform a safety assessment of an additive product which is an end product, since this is different from the case of genetically modified foods in which the recombinant is consumed as it is. Therefore, from this point of view, safety assessments of additives whose end product is a highly purified nonprotein additive, such as amino acids, are carried out in the following way:

Regarding additives whose end product is a highly purified nonprotein additive, such as amino acids, if all the requirements shown in 1 and 2 below are satisfied, generally speaking the confirmation of the safety of said additive will be deemed have been reached.

1. The purity of the product is equal to or greater than that of , for example, amino acids, nucleotides, vitamins, and monosaccharides, which are announced as a designated additive in a public notice.
2. Compared to conventional additives, the content of existing non-active ingredients have not increased significantly in said additive to a level that could cause a safety issue, and no new non-active ingredients suggested to be harmful are included.

In addition, it is essential that the overview of the production methods (methods for producing the genetically modified microorganisms, methods for extracting and purifying the additive), uses, chemical structure and composition, physiochemical properties, and quality of said additive are clarified.