Food Safety and Quality Assurance of Food Products

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In order to protect the health of consumers, each government establishes a variety of standards by which the safety of the food is ensured. Since manufacturers must comply with these standards, they establish the monitoring system of their whole manufacturing process. Regarding the standards, the government prescribes the maximum level for contaminants contained in the farm and marine products, conditions under which permitted substance can be used, and the specification of processed food and food additives, etc.. The standards for contaminants in the farm and marine products prescribes the upper limit of (1) the substances which is taken from the environment during growing (heavy metals, radionuclides, dioxin, etc.), (2) the substances which is produced during manufacturing process such as heating and smoking (Acrylonitrile, polycyclic aromatic hydrocarbon, etc.), (3) mycotoxins which is produced by fungi during storage (aflatoxins, etc.). On the other hand, regarding the food additives which is produced in the factory, regardless whether the substance originates from natural product or not, the safety assessment of the substance by the government is required at first, and based on the results, the authority establishes acceptable daily intake (ADI) and the conditions under which the substance can be used.

Since safety standards for agricultural products, processed foods, and food additives are based on the same idea, I would like to report on how safety of food is ensured by the government and food manufacturers by introducing the case of food additives produced by fermentation technology.

In case of food additives, the safety assessment is conducted by the government at first, based on the experimental data submitted by the applicant. If the substance is regarded as safe, it is approved for the use in the food. During the safety assessment, ADI is established based on the “no observed adverse effect level (NOAEL)”, and where necessary, the maximum level on which the substance can be used is determined on each food categories, depending on the amount of intake of those food categories. In addition to the safety assessment of the substance itself, the specification of the substance is also established in order to ensure the safety of manufactured products at any factories. The specification prescribes purity, assay method, the maximum limit of impurities such as heavy metals, derivatives, etc.. The products produced in the country must conform with the specification determined by the government. Many developing countries which cannot establish their own standards and specifications refer to the international standards such as Codex standards or JECFA specifications, which are established by subsidiary organization of the Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO). Since these international standards are also cited as reference by World Trade Organization (WTO) when international trade dispute is adjudicated, developed countries also refer and introduce these standards to those of their own.

On the other hand, the manufacturers are required to ensure the safety of the substance itself even at the post-marketing stage. Glutamate is one of the amino acids contained in tomato, cheese, seaweed, etc., and its sodium salt, so called MSG, is used as a flavor enhancer. Monosodium glutamate is produced by fermentation technology and has been used in the food for a long time, being classified as generally recognized as safe (GRAS) in the US. The international organization evaluated its safety to conclude that “ADI not specified” in 1987. However, ongoing debate exists after 1968, concerning whether MSG causes Chinese Restaurant Syndrome (CRS). In order to elucidate if MSG causes alleged reactions, Geha et al. performed multicenter, double-blind, placebo-controlled, multiple-challenge evaluation, recruiting 130 self-selected reportedly MSG-reactive volunteers in the US.[1,2)] The results suggest that large doses of MSG given without food may elicit more symptoms than placebo. However, neither persistent nor serious effects from MSG ingestion are observed. The frequency of the responses was low and not reproducible. The responses were not observed when MSG was given with food.

Regardless of the conformity of the product with the specification, sometimes severe health hazard occurs. Eosinophilia-Myalgia Syndrome (EMS) was caused by the health food mainly composed of L-Tryptophan produced by Showa Denko K.K., a Japanese manufacturer, during a specific period in 1989. Due to this hazard, more than 30 people died. Despite of the intensive research, the exact cause of the health hazard was not specified. Finally, it was concluded that the multiple factors including specific impurities caused EMS. After the specification of L-Trp were tighten, no EMS has been reported.

In order to comply with the standards and minimize the risk of hazardous effect, the manufacturer establishes the monitoring system of the whole manufacturing process. On the final part, I would like to introduce our assessment system by which the specification of the raw material and the final products, all the manufacturing process including packaging process is monitored.

(1) Geha RS, Beiser A, Ren C, Patterson R, Greenberger PA, Grammer LC, Ditto AM, Harris KE, Shaughnessy MA, Yarnold PR, Corren J, Saxon A., Multicenter, double-blind, placebo-controlled, multiple-challenge evaluation of reported reactions to monosodium glutamate. J Allergy Clin Immunol. 2000; 106(5):973-80.

(2) Geha RS, Beiser A, Ren C, Patterson R, Greenberger PA, Grammer LC, Ditto AM, Harris KE, Shaughnessy MA, Yarnold PR, Corren J, Saxon A., Review of alleged reaction to monosodium glutamate and outcome of a multicenter double-blind placebo-controlled study., J Nutr. 2000; 130(4S Suppl):1058S-62S.