FOOD SAFETY

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Advantame

Summary

Food Safety Commission of Japan

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of advantame (CAS number: 714229-20-6), a food additive used as a sweetener, based on results from various studies. FSCJ concluded that advantame and its degraded-products are of no concern in terms of their genotoxicity. In a prenatal developmental toxicity study in rabbits, dams administered advantame exhibited digestive disorders accompanied by deterioration of general conditions at doses of 1,000 mg/kg body weight/day or higher. FSCJ considered this effect attributable to the administration of advantame, and regarded 500 mg/kg body weight/day (a dose lower than that causing the above-mentioned effect) as the lowest no-observed-adverse-effect level (NOAEL) of advantame. In addition, advantame showed no carcinogenicity. Taking the observed toxicological effects and the estimated intake of advantame (3.57 mg/person/day (0.0714 mg/kg body weight/day)) after its approval in Japan into account, FSCJ considered that it is necessary to specify an acceptable daily intake (ADI) for advantame. FSCJ specified the ADI of 5.0 mg/kg body weight/day, based on the NOAEL in the prenatal developmental toxicity study in rabbits (500 mg/kg body weight/day) and applying a safety factor of 100.

Conclusion in Brief

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of advantame (CAS number: 714229–20-6), a food additive used as a sweetener, based on results from various studies. The results used in the assessment are on; toxicokinetics, genotoxicity, acute toxicity, repeated dose toxicity, carcinogenicity, reproductive and developmental toxicity, allergenicity and general pharmacology in experimental animals and human data on advantame as the test substance. FSCJ reviewed toxicokinetics of advantame in experimental animals, its general pharmacology and also data on humans, and concluded that these data showed no matters of concern for food safety. FSCJ concluded that advantame and its degraded-products are of no concern in terms of their genotoxicity. FSCJ reviewed the acute toxicity, repeated dose toxicity, carcinogenicity, reproductive and developmental toxicity and allergenicity of advantame. In a prenatal developmental toxicity study in rabbits, dams administered advantame exhibited digestive disorders accompanied by deterioration of general conditions at doses of 1,000 mg/kg body weight/day or higher. FSCJ considered this effect attributable to the administration of advantame, and regarded 500 mg/kg body weight/day (a dose lower than that causing the above-mentioned effect) as the lowest no-observed-adverse-effect level (NOAEL) of advantame. In addition, FSCJ concluded on the basis of its review that advantame showed no carcinogenicity. Taking the observed toxicological effects and the estimated intake of advantame (3.57 mg/person/day (0.0714 mg/kg body weight/day)) after its approval in Japan into account, FSCJ considered that it is necessary to specify an acceptable daily intake (ADI) for advantame. FSCJ specified the ADI of 5.0 mg/kg body weight/day, based on the NOAEL in the prenatal developmental toxicity study in rabbits (500 mg/kg body weight/day) and applying a safety factor of 100.

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