



Risk Assessment of Nitrosamines (NAs)

Nitrosamines (NAs) occur due to the reaction of secondary amines and nitrites under acidic conditions. They may be formed *in vivo* from precursors following the ingestion of foodstuffs, and bacteria in the gastrointestinal tract contribute to the formation of nitrosamines from nitrites and amines. Nitrosamines are listed as “probably carcinogenic to humans” (Group 2A) and “possibly carcinogenic to humans” (Group 2B) by the IARC. Studies have shown that, when administered orally, nitrosamines are quickly absorbed in the gastrointestinal tract, and their metabolites exhibit carcinogenicity in hamsters and rats. When 12–30 µg of N-nitrosodimethylamine in drinking water containing ethanol was administered to humans, 0.5–2.4% of it was excreted in urine within 24 h.

Residual hazardous substances in food that are formed during food manufacturing, processing, or cooking, and remain in the foods afterward, may pose a threat to food safety, even in small amounts, as they tend to be ingested for a lifetime. This has heightened anxiety over food safety among the Korean people. Under the existing monitoring system for hazardous substances, the content of a hazardous substance in uncooked food is measured to estimate its exposure dose based on the monitoring results. This approach fails to capture the true content of a harmful substance accurately because of changes that occur during the cooking process, where concentrations can be increased or decreased due to both physical and chemical interaction. For this reason, this risk assessment determined daily exposure doses more accurately based on a TDS, which estimates daily intakes through an analysis of table-ready foods, or an analysis of the content of hazardous substances. A quantitative assessment of potential health risks was also performed.

This risk assessment was carried out in accordance with the Regulations on Risk Assessment

2016 SCIENTIFIC REPORT



MINISTRY OF FOOD AND DRUG SAFETY

National Institute
of Food and Drug Safety Evaluation

Methods and Procedures, as well as the Risk Assessment Guide, in the following four stages: hazard identification, hazard characterization, exposure assessment, and risk characterization. Target foods were selected from the 2008–2013 (six years) Integrated Database, and this study covered 97.4% of the total food intake of Koreans and 98% or more of their energy, protein, fat, and carbohydrate intakes. A final set of 1,227 sample pairs was selected (291 pairs from agricultural products, 96 from livestock products, 233 from fishery products, and 607 from processed foods) after adding food commodities intended to be eaten uncooked (raw) with the “food and cooking method pairs.” The analysis of nitrosamines present in food was performed using GC-MS, and samples of the food items, purchased across the country, were combined to create composite samples. One sample was analyzed for each cooking method per food, and the pairs from which a nitrosamine was not detected were considered to have a zero content.

Results of the TDS-based risk assessment showed that dietary exposure to nitrosamines is 0.0189 $\mu\text{g}/\text{kg}$ bw/day, which is about 81.1% of the level for the German population. Major food commodities contributing to nitrosamine exposure include napa cabbage kimchi, potatoes, doenjang (soybean paste), pepper powder, tianmianjiang (sweet bean sauce), processed pork (ham), and confectionery (snack confectionery).

There have been few studies to assess dietary exposure to nitrosamines. Since there is no HBGV for nitrosamines, it is necessary to observe trends in dietary exposure levels through continuous monitoring.

Key words: N-nitrosodimethylamine, NAs, Foods, Risk Assessment, Total Diet Study, Reduction