MINISTRY OF FOOD AND DRUG SAFETY
National Institute
of Food and Drug Safety Evalution

Risk Assessment of Biogenic Amines (BAs)

Biogenic Amines (BAs) are nitrogenous compounds formed mainly by the decarboxylation of amino acids or by the amination and transamination of aldehydes and ketones during the metabolic processes of microbes, plants, and animals, and are naturally found in live cells. Biogenic amines are found in fermented soybean products, kimchi, fermented livestock products, and fish. Histamine, the most well-known biogenic amine, is used as an indicator of hygiene to measure the extent of decomposition in fish. The Codex standard for histamine levels in fish and processed fish products is set at less than 100 ppm. Putrescine, spermidine, tyramine, tryptamine, and cadaverine can react with nitrites in food to form a carcinogen called nitrosamine. Once administered parenterally, histamine is readily absorbed by the body. Tyramine is not absorbed in the intestines, but is readily absorbed when administered hypodermically and its half-life *in vivo* is quite short. The diverse metabolites of histamine have little pharmacological activation, and most of them are passed out of the body in urine.

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 interactions. 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 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 1,221 sample pairs was selected (289 pairs from agricultural products, 96 from livestock products, 233 from fishery products, and 603 from processed foods) after adding foods that were intended to be eaten uncooked (raw) with the "food and cooking method pairs." The analysis of BAs present in food was performed using liquid chromatography with an ultraviolet detector, and samples of the food commodities, 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 biogenic amines were not detected were considered to have a zero content.

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There is no HBGV set for BAs. For this reason, the toxicity benchmark value of $BMDL_{10}$

36,920 μg/kg bw/day, proposed by the Codex for histamine, was also applied here to estimate the margin of exposure for BAs. The results of the assessment showed that dietary exposure to BAs is being maintained at safe levels, with findings similar to, or lower, than those of Japan, Australia, and the European Food Safety Authority (EFSA). Contributors to BA exposure include soju, beer, canned tuna, ramyeon (instant noodle), makgeolli (rice wine), kimchi (napa cabbage kimchi), soybeans, and garlics. Contributors to histamine for which a standard exposure level is set include white rice at 21.5%, kimchi (napa cabbage kimchi) at 20.3%, and ssamjang (mixed paste) at 13.5%. The food and cooking method pairs with the highest histamine content is pepper powder (boiled), followed by pepper powder (prepared by grilling and frying) and aekjot (liquid salted and fermented seafood) made of fish and shellfish (as is/pan-fried/boiled).

To reduce the formation of BAs in food during manufacturing and processing, the MFDS recommends (1) lowering fermentation and storage temperatures, (2) selecting high-quality strains for fermentation, and adding additives to the processing steps during manufacturing. It is necessary to continue identifying trends in exposure levels through constant monitoring and risk assessment of BAs. Methods for setting HBGV criteria and standards should be discussed, and BA exposure control levels should be based on those results.

Key words: Histamine, BAs, Foods, Risk Assessment, Total Diet Study, Reduction