

2016 SCIENTIFIC REPORT



MINISTRY OF FOOD AND DRUG SAFETY

National Institute
of Food and Drug Safety Evaluation

Risk Assessment of Ethylene Oxide (EtO)

Ethylene Oxide (EtO) is a flammable, colorless gas that can take the form of a cooled liquid. This extremely flammable, toxic, and irritating substance with a slightly sweet odor is a residual compound that remains after fumigation. Ethylene bromohydrin, and other products, can be formed by physical absorption or by reaction with a chlorinated inorganic compound in food. It is also present in nature. In certain plants, ethylene (a natural plant growth regulator) is degraded to EtO. It is also a product of ethylene catabolism in certain microorganisms. EtO and its secondary products, ethylene chlorohydrin and ethylene glycol, cause the most concern, as they are carcinogenic, and 90% of this carcinogenicity is reported as mutagenicity. Chronic exposure to EtO, or the long-term intake of food treated with EtO, may increase chromosomal aberrations, inducing spontaneous abortion, mutation, congenital abnormalities, leukemia, and cancer. EtO exposure by inhalation causes almost 100% of the inhaled gas to be absorbed, and then quickly removed. During the first 24 h after inhalation, 74% is excreted in urine as metabolites, while 4% is passed out in the following 24 h. The IARC has classified ethylene oxide as “carcinogenic” to humans (Group 1).

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

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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 1,227 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 EtO present in food was performed using GC-MS, 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 EtO was not detected were considered to have a zero content.

The TDS-based risk assessment was conducted by applying the no observed adverse effect level of 7,500 $\mu\text{g}/\text{kg bw}/\text{day}$ for EtO to estimate the margin of exposure. Based on the results, dietary exposure to EtO was determined to be at safe levels. The detection rate of EtO is about 1.38%, and it was not detected in agricultural or fishery products. For Koreans, the daily exposure dose of EtO was measured at 0.447 $\mu\text{g}/\text{kg bw}/\text{day}$, and the top contributor to EtO exposure is flavor enhancers (96.1%), of which pepper accounts for 96.0%. The list of foods and cooking method pairs with the highest EtO content was topped by pepper powder prepared using the five cooking methods previously described. However, as eating habits change, or as the environment changes, exposure levels may exceed the margins of safety. Therefore, it is necessary to continue monitoring exposure trends and reducing exposure

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levels by finding methods to reduce the formation of EtO during cooking or manufacturing, and by focusing on foods whose exposure levels show an upward trend.

Key words: Ethylene oxide, Foods, Risk Assessment, Total Diet Study, Reduction