Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration
PHILIPPINES

FDA STATEMENT
11 JULY 2022

ACTIONS RELATIVE TO THE EU-RASFF ALERT ON LUCKY ME! INSTANT NOODLE PRODUCTS MANUFACTURED IN THAILAND

The FDA received a copy of the European Union Rapid Alert System for Food and Feed (EU-RASFF) that Lucky Me! instant noodles manufactured in Thailand are being recalled in Ireland, Malta, and France due to the presence of residual ethylene oxide.

In the Philippines, Lucky Me! is registered with the FDA as a food product. The Certificate of Product Registration (CPR) holder and FDA-licensed manufacturer is Monde Nissin Corporation.

Following the Rapid Alert from EU, the FDA initiated an investigation to determine if the locally produced Lucky Me! Instant Noodle Products are likewise affected.

Ethylene oxide is present in the environment. It comes from various sources, including plants and the heating of cooking oils. The human body also converts ethylene to ethylene oxide.

One of the most important uses of ethylene oxide gas sterilization in agricultural products is to destroy Salmonella to prevent foodborne outbreaks of Salmonellosis, which is easily spread through contaminated agricultural products that are traded internationally.

Ethylene oxide is most commonly used in the production of other chemicals including the production of solvents, antifreeze, detergents, adhesives, polyurethane foam and pharmaceuticals.

A very important use of ethylene oxide in the medical field is the gas sterilization of surgical and medical equipment, including the sterilization of personal protective equipment (PPE). It is estimated that ethylene oxide sterilizes billions of medical devices each year to prevent the spread of disease and infection. There are procedures post-gas sterilization that are followed by manufacturers to prevent violative level of residual ethylene oxide.

Consumption of foods containing residual ethylene oxide does not pose an acute risk to health. However, there is an emerging concern that continued exposure beyond the tolerable level over a long period of time may result in health issues.

In this regard, the EU adopted a zero tolerance for ethylene oxide, claiming that there is no safe level of exposure for consumers in products that contain residual ethylene oxide. EU believes that any level of residual ethylene oxide in packets of seasoning of instant noodles presents higher risk to consumers.

Other nations, however, like the United States, Canada and Singapore, have assigned tolerance level for residual ethylene oxide ranging from 7 ppm to 50 ppm maximum residue limit (MRL). In the Philippines, ethylene oxide gas is allowed for gas sterilization of certain agricultural products. Such use is allowed in the PHILIPPINE NATIONAL STANDARD PNS/BAFS (Bureau of Agriculture and Fisheries Standards of the Department of Agriculture) 149:2015; ICS 67.020, The Code of Hygienic Practice for Spices and Dried Aromatic Herbs.

The FDA already convened series of meetings to evaluate the EU report and its implications. It has already been confirmed that Monde Nissin Corporation is compliant with food safety based on Hazard Analysis Critical Control Points (HACCP)/Good Manufacturing Practice (GMP) requirements based on latest inspections (March 2022; July 2022).

To further assure food safety, the local manufacturer is in the process of verifying the level of residual ethylene oxide in the packets of seasoning. The FDA food inspectorate has already conducted spot check inspections and collected samples for laboratory analysis. The FDA shall wait for all information, including laboratory results, before taking further action. In the meantime, the FDA will continue to coordinate with the manufacturer and to monitor the situation.

The FDA remains committed to collaborate with the DA-BAFS, DTI-BPS, the private sectors, the academe, and food scientists, researchers and experts to update its science-based policies and regulation to prevent potential and real food contaminants for the protection of public health. The FDA supports the safer alternatives for disinfecting certain agricultural products.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General