Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

17 January 2014

FDA ADVISORY
No. 2014-007

SUBJECT: Public Caution Against Laboratory Reports on Levels of Lead (Pb) in Toys Using Handheld XRF Instrument

The FDA is seriously concerned over the "field laboratory reports" generated by handheld or portable X-ray fluorescence (XRF) instruments and released to public by some well meant organizations. Reports on the levels of lead (Pb) in some samples of toys may have some accuracy and precision issues, as well as erroneous interpretation of the values in toys.

In the FDA Advisory No. 2013-042 re Consumer Information on How Lead (Pb) from Toys Can Gain Entrance in the Body, and Some Tips for Parents, it was explained that Pb gains entrance in the body when ingested. When Pb is incorporated in plastic toys, it does not rub off easily because it is chemically bonded with the plastic i.e. Pb is not bioavailable and does not migrate or leach even on the hands. Lead in toys is not absorbed through the skin, but paints containing lead which are rubbed from toys can be a source of Pb dust that can be inhaled or ingested.

The XRF field results provide for the total lead content reading of the product as screened by the instrument, whereas FDA laboratory analysis is in accordance with the Philippine National Standard PNS-BHDT ISO 8124-3:2008: Safety of Toys - Migration of Certain Elements, which is able to determine the migratable lead on accessible parts or components of toy products. Migratable lead is the level wherein there is great possibility of real risk that the lead (Pb) in toys may be ingested. Total lead is not the same as migratable lead. Canada, for example, is known to have the strictest regulations in toys, but in 2005, under authority of the Hazardous Products Act, the Children's Jewellery Regulations, Canada allowed importation, advertisement or sale of jewelry for children under 15 years of age if the jewelry does not contain more than 600 mg/kg total Pb and 90 mg/kg migratable Pb.

The FDA Central Laboratory in Alabang is the first government laboratory conducting physico-chemical tests and microbiological analysis that was granted an ISO:17025 Certificate by the DTI Philippine Accreditation Office. Majority of the FDA analysts are DTI-PAO approved chemical or microbiological signatories. Currently, the laboratory continuously conducts verification of XRF screening results on toy products against laboratory testing, since there is no direct relationship between them. The XRF analyzers may have the ability to quickly provide rapid screening solution, but has limitations in its accuracy due to various factors that may affect the results. The primary goal is not necessarily to accurately analyze the chemical composition of all components or parts of the product, but to weed out or eliminate from the market products containing restricted elements. This complements rather than replaces lab testing, allowing for an optimized process for finding problem consumer products.

To assure the quality of toy products and ensure the children's highest level of protection, FDA requires compliance with the Philippine National Standards (PNS) ISO 8124: Safety of Toys Parts 1- 3. Part 1 refers to safety aspects of Mechanical and Physical Properties, Part 2 on Flammability and Part 3 on Migration of Certain Elements (Chemical Safety). These standards must be satisfied before any toy product can have market authorization. However, it is not intended to eliminate parental responsibility or supervision in the appropraiate selection of toys.

The public is hereby cautioned to exercise their power of discernment before accepting laboratory data or information generated by non-accredited laboratories or unauthorized laboratory analysts. Validation may be requested from a third party laboratory or any DTI-PAO-accredited laboratories. Interpretation or analysis of laboratory findings involving the presence of chemical or microbiological hazards in health products is a scientific or technical pursuit which should be done by knowledgeable, trained and experienced people. There are other considerations in assessing the health risks of an identified hazardous substance, such as characterization of the hazard, in the case of lead (Pb) if its migratable Pb or not; assessesment of exposure based, among others, on the age and activities of the population; characterization of the real risk; as well as other possibilities or uncertainties.

For more information and clarification, please contact us via info@fda.gov.ph.

KENNETH Y. HARTIGAN-GO, MD
Acting Director General