

GETTING THE LEAD OUT – AGAIN: LEAD IN FDA REGULATED PRODUCTS

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The intentional use of lead (Pb) as an indirect food additive is allowed in some FDA regulated products (e.g., in tableware glazes and decorations). Other prior uses (e.g. in Pb-based can solders and Pb-based pesticides), are prohibited. Pb is occasionally found in products such as foods, Asian patent medicines, cosmetics, and devices. While in some cases these are intentional additions, e.g. some Asian patent medicines and cosmetics), in most cases it is a component due to unforeseen and often preventable contamination of the product. For tableware where Pb use is still allowed, FDA has established “action levels” for leachable Pb. XRF can provide valuable information as to the composition of tableware. It can be used for determining its location, as well as determining the presence of other elements that are known to affect the stability of Pb-based glazes. “High risk” wares such as folk terra cotta from Mexico are particularly hazardous because the user cooks, stores, and serves food in these wares. Some traditional wares from China that utilize Pb-based enamel over porcelain have been found to leach thousands of ppm. XRF can also indicate the presence of other potentially toxic elements (Cd, Se, Co, Ba), which if leachable, could cause a potential hazard. Additionally, some tin and brass-based alloys contaminate foods because of their lead content. Although prohibited, Pb-based solders are occasionally seen primarily in ethnic food products from Eastern Europe. Occasionally, brass fixtures come in contact with acidic beverages resulting in food contamination. Some re-usable beverage bottles used in foreign countries have high levels of Pb on the exterior surfaces and occasionally enter U.S. commerce. While the beverage in these bottles has not shown high levels of Pb, the external surfaces bear a highly leachable form of Pb, especially when the bottle decoration has become eroded from washing. Typical “hand-to-mouth” transfer of lead would be expected if children drank from these bottles. Foods rarely contain levels of Pb that are detectable by XRF or levels that pose a potential risk of excessive exposure. However, when foods do contain significant levels, they usually arise from unsanitary conditions and/or poor quality control of products. In rare cases, some cosmetics, devices, and Asian patent medicines have been found to contain relatively high levels of Pb, occasionally percent levels. This presentation will highlight these FDA applications and demonstrate how field portable and lab-based XRF methods can be used to either screen for Pb in these products or provide reliable quantitative results as the basis for regulatory action.