Response to FDA Docket No. 2005D-0481

As one of the authors, of the recent American Public Health Association's resolution on lead in candy, I wish to applaud the FDA's intent to set a lead in candy guidance level at 0.1 ppm.[1] The FDA should also be commended for its proposal to set a 0.1 ppm guidance level for lead in salt-based candy, which was a food item that had no previous FDA lead guidance level.

This proposed regulatory guidance level is clearly warranted. This proposed guidance level for lead in candy will help to achieve the FDA's recommended 6 micrograms per day tolerable limit for dietary intake of lead for children age 6 years or younger.[2] Under the FDA current guideline, of 0.5 ppm of lead in candy, a child would only have to consume one 12 gram candy bar to ingest 6 micrograms of lead. However, under the proposed guideline, of 0.1 ppm of lead in candy, a child would have to consume two 30 gram candy bars to ingest 6 micrograms of lead.

Setting a guidance level for lead in candy at 0.1 ppm is also consistent with the National Academy of Sciences (NAC) maximum lead level recommendation of 0.1 ppm for lead in sucrose (sugar).[3] The lead level in candy should not exceed the NAC recommended maximum lead level in sugar since candy, unlike sugar, is not normally diluted before ingestion. In addition, recent scientific evidence clearly demonstrates the toxicity of lead to young children at levels well below the current Centers for Disease Control and Prevention blood lead "level of concern" standard of 10 micrograms per deciliter.[4,5] Therefore, a reduction in the FDA guidance level to 0.1 ppm for lead in candy is warranted based on the current scientific knowledge of the toxicity of lead.

My main concern, with this proposed guidance level, is that the FDA will fail to take enforcement action when if finds a candy product that repeatedly exceeds its guidance level. Hopefully, the FDA will take enforcement action when a candy product continually exceeds this 0.1 ppm lead guidance level. In addition, once a candy manufacturer markets a product as a candy-type product, then the FDA should presume this product is being eaten by children in candy-type quantities. The burden should be on the candy manufacturer to show that their product, which is being marketed as a candy-type product, is not being consumed by children in candy type quantities.

Sincerely,

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[1] American Public Health Association Policy No. 2005-7: Protecting Children from Overexposure to Lead in Candy and Protecting Children by Lowering the Blood Lead "Level of Concern" Standard. http://www.apha.org/legislative/policy/policysearch/index.cfm?fuseaction=view&id=1320 (Accessed January 22, 2006).

[2] Carrington CD, Bolger PM. Division of Toxicological Review and Evaluation (HFF-156), Food and Drug Administration. An assessment of the hazards of lead in food. Regul Toxicol Pharmacol 1992;16:265-72.

[3] Food Chemicals Codex, Fifth Edition, National Academies Press, Washington, D.C., 2003:455-456.
[4] Canfield RL, Henderson CR, Cory-Slechta DA, Cox C, et al. Intellectual impairment in children with blood lead concentrations below 10 mg per deciliter. N Engl J Med 2003; 348: 1517-26.
[5] Lanphear BP, Hornung R, Khoury J, et al. Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. Environ Health Perspect. 2005;113(7): 894–899. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1257652 (Accessed January 22, 2006).