
Advisory Committee on Childhood Lead Poisoning Prevention

Lead in Candy

**Michael Kashtock, P. Michael Bolger, and Terry Troxell
FDA/CFSAN**

October 26, 2006

Lead Reduction Efforts in Food

- Phase out of leaded gasoline and lead soldered cans in 1980's were major advances.
- Dietary lead exposures have been reduced dramatically since that time with reductions of about 95% as compared to the 1970s.
- Current exposure levels for the U.S. range from 1.4 to 2.4 $\mu\text{g}/\text{day}$.
- FDA has also addressed other contributions to dietary exposure such as infant formula, fruit juices, ceramicware, wine, bottled water and candy among others.
- Particular emphasis has been placed on those foods consumed by pregnant women and children.

Lead in Candy Wrappers

- In mid 90's some imported candy products were found to be contaminated from lead based ink used in wrappers.
- FDA issued a 1995 guidance letter stating that lead based ink used on wrapper that migrates to candy causes food to be adulterated.
- FDA unaware of occurrences of lead based ink migrating into candy since mid 1990's.
- Use of lead ink on a wrapper that does not migrate to candy is not actionable under FDA's laws, but can be evaluated by CPSC as a hazardous consumer product, e.g., lead transfers to hand and to mouth at a hazardous level.

Lead in Mexican Candy

- ✱ In its 1995 letter FDA also set a guidance level for maximum lead level in candy of 0.5 ppm.
- Most candy products tested by FDA contain lead levels well below 0.5 ppm.
- ✱ Sampling has shown a few Mexican candy products containing significant amounts of chili and/or salt to contain > 0.5 ppm lead (highest levels found have been ~ 1 ppm).
- Such products are currently subject to enforcement action if identified.
- ✱ Current border sampling places high emphasis on these types of Mexican candy products.
- If such candies do enter U.S. consumption of such candies are estimated to result in increases in blood levels below 10 $\mu\text{g/dL}$.

Lead in Mexican Candy

- Source of lead in these products:
 - Chili peppers not washed to remove soil borne lead
 - Use of salt from some sources that contain higher lead levels (but still within FCC specification)
- FDA believes that manufacturers of such candy should utilize GMPs in sourcing of ingredients and manufacturing to ensure that lead levels in candy are as low as feasible
- In March 2004, FDA announced its intent to lower its guidance level for lead in candy, noting some of these findings for Mexican candy
- April 2004, FDA issued advise to parents to not let children consume chili candy, powdered snack mixes and tamarind candy packed in ceramic bowls.

Rationale for new guidance level

- FDA recognizes that some types of Mexican candy have been found to contain levels of lead that are the result of avoidable lead contamination
- We want firms to reduce lead levels in types of candy to levels that are achievable/feasible under GMP
- Ensure that lead in candy does not pose a health risk to children

What lower guidance level will do

- Induce producers of chili and salt containing Mexican candies to control the lead levels in these candy ingredients.
- Induce producers of other types of candy that occasionally contain elevated lead levels to review practices to more consistently achieve lowest levels of lead that are practically achievable
- Little change anticipated for candies that contain essentially sugar, due to extremely low lead levels consistently found in sugar

Estimated lead exposures

- Sugar based candies – Lead intake for 90th percentile males and females under 6 yrs. old will be $< 0.1 \mu\text{g}/\text{day}$
- Chocolate - Lead intake for 90th percentile males and females under 6 yrs. old will be $< 1 \mu\text{g}/\text{day}$
- Traditional style Mexican candies, 15% chili, Lead intake for 90th percentile males and females under 6 yrs. old will be $< 1.5 \mu\text{g}/\text{day}$

Why the differences

- Sugar is a highly refined ingredient, i.e. solution and re-crystallization
- Chocolate does not undergo as extensive a refining process as sugar, the chocolate liquor is produced from the cocoa bean by roasting/grinding
- Lead that remains on a chili pepper after washing is concentrated six-fold by the drying of the pepper
- Therefore different ingredients will contain differing amounts of lead, even if GMP is employed in producing the ingredient

Status of Guidance

- Drafted
- Internal review “well along”
- Expect publication of draft for public comment before the end of 05
- Will follow with final guidance after comment period. Project final guidance in 06

Other ongoing activities

- FDA provides assistance to state and local governments:
 - Recommendations on analytical methodology
 - Review of test results
 - Commenting on public advisories