Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children

[Docket No. 2005D-0481]

U.S. Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition (CFSAN)

December 2005

Table of Contents

I. Introduction

II. Overview of FDA Activities Addressing Lead in Food

III. FDA Actions Addressing Lead in Candy and Candy Wrappers

IV. Lead Levels Found in Candy

- a. Sugar-Based Candy
- b. Chocolate Candy
- c. Mexican-Style Candy
  - i. With Chili as an Ingredient
  - ii. Salt-Based Powdered Snack Products
  - iii. With Tamarind Pulp as an Ingredient
- d. Other Candy Ingredients and Other Types of Candy

V. Health Protection Considerations

- a. Sugar-Based Candy
- b. Chocolate Candy and Other Non-Mexican Types of Candy
- c. Mexican-Style Candy
  - i. With Chili as an Ingredient
  - ii. Salt-Based Powdered Snack Products
  - iii. With Tamarind Pulp as an Ingredient

VI. References

I. Introduction

The purpose of this document is to further present the background and rationale for FDA's recommended maximum lead level in candy likely to be consumed frequently by small children. The 0.1 parts per million (ppm) recommended maximum lead level in candy described herein is included as a part of the 2005 updated FDA guidance on lead in candy entitled "Lead in Candy Likely To Be Frequently Consumed by Small Children: Recommended Maximum Level and Enforcement Policy," available at http://www.cfsan.fda.gov/~dms/guidance.html. FDA considers the recommended maximum lead level to be achievable and to be protective of public heath.

II. Overview of FDA Activities Addressing Lead in Food

Lead is a naturally occurring element whose toxicity in humans has been documented throughout history.

Lead is widely present in our environment due to its natural occurrence and human activities that have introduced it into the general environment such as the use of leaded gasoline. Because lead may be present in environments where food crops are grown and animals used for food are raised, various foods may contain unavoidable but small amounts of lead that do not pose a significant risk to human health.

However, foods may become contaminated with lead if they are grown, stored or processed under conditions that could introduce larger amounts of lead into the food, such as when a root crop is grown in soil that has been contaminated from the past use of leaded pesticides on that acreage. Under such conditions, the resulting contamination of the food may pose a health risk to consumers.

FDA first recognized the need to control potential lead exposure from food in the 1930s. The earliest actions of the agency focused on limiting the potential for lead to become a component of food as a consequence of intentional uses of lead containing substances in agriculture and food processing, e.g., lead-based pesticides and lead containing solder in food cans. (Ref. 1)

During the 1970s and 1980s studies were published documenting adverse effects of lead in children at lower blood lead levels than had been previously established. In 1979, FDA stated that it intended to expand its programs to monitor and reduce lead levels in the food supply with the objective of reducing consumer's lead exposure to the lowest level that can be practicably obtained. (Ref. 2)

The goal of limiting lead contamination of food was facilitated by the development and implementation of the use of welded (non-soldered) food cans during the 1980s. This development and the concurrent prohibition of the use of lead containing gasoline in the

U.S. are largely responsible for dramatic decreases in measured lead levels in the U.S. diet beginning in the 1980s. (Ref. 3)

FDA's past and current activities intended to reduce or limit lead levels in food have addressed pesticides, lead glazed ceramic ware and other house wares, bottled water, wine, food cans, food additives, candy and candy wrappers.

III. FDA Actions Addressing Lead in Candy and Candy Wrappers

Candy products were not known to be a significant food source of lead until 1994, when California authorities found that an imported candy product from Mexico was contaminated with lead that had migrated into the candy from lead-based ink used in the candy's packaging. The package was poorly designed such that its inner coating did not maintain its structural integrity, allowing lead-based ink in the outer package layer to migrate into the candy.

Subsequently, FDA began testing other candy products with lead-based printing inks on their packaging to determine whether lead from the ink was migrating into the candy. In its testing, FDA discovered that, apart from any consideration of the wrapper as source of the lead, some imported candy products from Mexico contained higher lead levels than were typically found in domestic candy products. As discussed below, FDA determined that the higher lead levels were largely associated with certain ingredients used in these imported candy products.

Prompted by these findings, in 1995 FDA issued a letter entitled "Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers," ((the 1995 letter) available at http://www.cfsan.fda.gov/~dms/pbguid.html), addressing its concerns about lead in candy derived from both candy wrappers and candy ingredients.

Concerning lead in candy derived from sources other than the wrapper, e.g., lead from candy ingredients, FDA advised manufacturers, importers, and distributors of imported candy, that where frequent consumption of candy products by small children could be anticipated, the agency would consider taking regulatory action against candy with lead levels that exceeded 0.5 parts per million (ppm). The 0.5 ppm guideline was, at that time, equivalent to the Food Chemicals Codex (FCC) specification for lead in sucrose (sugar), the main ingredient in many candy products.[1]

Many candy products contain sugar or chocolate as principal ingredients. Sugar (sucrose) is made by a process, i.e., re-crystallization, which when carried out under good manufacturing practices, typically results in low parts per billion (ppb) (1 ppb is equivalent to 0.001 ppm) or undetectable lead levels in the final product. Consequently, FDA typically finds low parts per billion or undetectable levels of lead in sugar-based

[1] The FCC is a compendium published by the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences, which contains food-grade specifications for food ingredients; in most cases, these specifications are eventually incorporated into relevant FDA regulations. Since we issued the 1995 letter, the FCC specification for lead in sucrose has been reduced from 0.5 ppm to 0.1 ppm.

candies it analyzes in its monitoring activities. While the manufacture of chocolate does not involve a re-crystallization process, most finished milk chocolate products contain lead levels well below 0.1 ppm.

Many Mexican-style[2] candy products can contain significant amounts of chili powder (hereafter, chili). At the time we issued the 1995 letter, we were aware that candy products with ingredients, such as chili, may contain more lead than sugar-based candies because chili is a minimally refined ingredient which would not be expected to contain lead levels as low as those in highly refined ingredients like sugar.

Since the issuance of the 1995 letter, however, we have found several candy and related products, i.e., "powdered snack mix" products (described below) containing chili to be contaminated with levels of lead that suggest that good manufacturing practices are not being employed in the manufacture of the chili ingredient, resulting in significant contamination of the chili ingredient and finished candy products with lead.

These findings of elevated levels of lead in candy and powdered snack mix products and our belief that such lead contamination is avoidable led FDA to issue a letter to the industry on March 25, 2004 (the 2004 letter, available at http://www.cfsan.fda.gov/~dms/pbltr.html) in which FDA announced that it intended to lower the 0.5 ppm guideline for considering enforcement action against candy products containing lead and likely to be consumed frequently by small children.

Concurrent with this document, FDA has issued a draft guidance document entitled "Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy." This draft guidance document, available at http://www.cfsan.fda.gov/~dms/guidance.html, announces a recommended maximum level for lead in candy likely to be consumed frequently by small children of 0.1 ppm. The draft guidance also rescinds the .5 ppm guideline for considering enforcement action and does not announce a new enforcement guideline.

IV. Lead Levels Found in Candy

a. Sugar-Based Candy

As noted above, FDA typically finds undetectable or low parts per billion levels of lead in most sugar-based candies it analyzes. For example, during the period late-1991 through 2002, FDA collected and analyzed 40 samples of suckers (lollipops of various

[2] "Mexican style" refers to candy which contains ingredients popular in Mexico such as chili and tamarind, which are not typically found in domestic candy in the U.S. We have included within the broad category of Mexican-style candy, powdered snack mix products, which are generally made in Mexico and typically contain combinations of salt, chili powder, sugar and flavoring. These products, popular with children and adults, may be sold alongside of candy in retail outlets, and can be consumed directly from the container like candy, as well as being sprinkled onto fruits and vegetables or in beverages.

flavors) as components of market baskets in its Total Diet Study (TDS) program.[3] Of the 40 sucker samples analyzed, FDA did not detect lead in 33 samples, and detected lead at levels too low to reliably quantify (referred to as a "trace" levels) in 7 samples. Based on all 40 results, the mean (average) estimated lead level was 4 ppb, with a standard deviation of 9 ppb and a maximum estimated trace value of 38 ppb. For granulated white sugar samples collected in the TDS during the same period, FDA did not detect lead in 39 of 40 samples it analyzed, and found a trace level of 18 ppb in the remaining sample. These results are what we would expect to find in sugar and sugar-based foods, consistent with the current FCC specification for lead in sucrose (sugar) of 0.1 ppm (100 ppb) because food ingredients typically are manufactured to contain average levels of contaminants that are well below the applicable limit to ensure that lots of the ingredient containing lead at the high end of the production range will still be below the applicable limit. Accordingly, FDA believes that sugar-based candy products can be made with lead levels below 0.1 ppm.

b. Chocolate Candy

FDA's TDS data on milk chocolate candy during the period mid-1991 through 2002 indicate that the mean lead level in 40 samples of milk chocolate candy bars was 0.025 ppm, the standard deviation was 0.018 ppm, and the maximum lead level found was 0.110 ppm. Data provided to FDA by the chocolate industry in 2005 (Ref. 4) indicate that the mean lead level in 137 milk chocolate samples (consisting of 7 products) was 0.028 ppm, the standard deviation was 0.022 ppm, and the maximum lead level found was 0.222 ppm. The industry data showed one additional sample with a lead level slightly greater than 0.1 ppm; all other lead levels in products tested were below 0.1 ppm.

The chocolate industry data indicate that the mean lead level in 226 dark chocolate samples (consisting of 9 products) was 0.048 ppm, the standard deviation was 0.029 ppm, and the maximum lead level found was 0.275 ppm. Several dark chocolate samples had lead levels exceeding 0.1 ppm, and more dark chocolate than milk chocolate samples had lead levels approaching 0.1 ppm. Dark chocolate samples tended to have higher lead levels than milk chocolate samples because chocolate liquor is the principal source of lead in chocolate products, and dark chocolate products contain higher amounts of chocolate liquor than milk chocolate products.

We believe that if milk chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed 0.1 ppm lead. With respect to dark chocolate, we expect lead levels to be higher than lead levels in milk chocolate due to the higher chocolate liquor content of dark chocolate. However, we believe that the consumption of dark chocolate products by children is limited. Results of the United States Department of Agriculture's (USDA's) 1994-96, 1998 Continuing Survey of Food

[3] The Total Diet Study is a program that has been conducted continuously by the FDA since the 1960s to among other things, monitor levels of chemical contaminants in foods and to estimate the dietary intake of these contaminants. FDA Total Diet Study data cited in this document are available at http://www.cfsan.fda.gov/~comm/tds-res.html.

Intakes by Individuals (CFSII) indicate that less than 1% of the children under age 6 surveyed consumed dark chocolate. We believe that, if dark chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed 0.1 ppm.

c. Mexican-Style Candy[4]

i. With Chili as an Ingredient

As noted above, we have found elevated levels of lead in Mexican-style candy products that contain chili. For example, from October 2000 to February 2004, we analyzed 132 candy products from Mexico, including powdered snack mix products for lead as part of our imported foods monitoring activity (Ref. 5). Fifty-two of these products had no detectable lead, while 51 had detectable levels of lead that did not exceed 0.150 ppm. Eleven products had lead levels in the 0.151-0.250 ppm range while eighteen had lead levels greater than 0.250 ppm. Among the latter group, 10 of the 18 products contained chili, and based upon visual observation, we believe that some contained significant amounts of chili.[5]

When monitoring for lead levels in its TDS, FDA typically finds that fresh peppers contain lead at non-detectable levels or trace levels. During the mid-1991 through 2002 period, FDA analyzed 40 samples of raw green peppers in its TDS and did not detect lead in 37 samples, while it detected trace levels of lead in 3 samples with a maximum estimated level of 14 ppb. Although FDA currently has only limited data on chili peppers, because chili peppers are similar in physical characteristics to green peppers, we believe that freshly grown raw chili peppers are not likely to be inherently contaminated with lead. Industry has, however, reported to FDA that chili can become contaminated with lead when soil deposits (which contain some level of lead) that accumulate on peppers from their growing and handling in open fields, are not removed by a washing step prior to grinding the dried peppers into chili powder. (Ref. 6). The lead introduced by the deposited soil is further concentrated by the drying of the peppers.[6]

Information reported to FDA by the industry indicates a broad range of lead levels in finished chili available in Mexico, and that higher levels of lead are present in chili from unwashed peppers (Ref. 6). Chili made from washed peppers averaged 0.241 ppm lead (range 0.023 to 1.14 ppm) while chili made from unwashed chili peppers averaged 0.938 ppm lead (range 0.049 to 2.21 ppm). These data suggest that Mexican-style candy

---

[4] We have included within the broad category of Mexican-style candy, powdered snack mix products, which are generally made in Mexico and typically contain combinations of salt, chili powder, sugar and flavoring. These products, popular with children and adults, may be sold alongside of candy in retail outlets, and can be consumed directly from the container like candy, as well as being sprinkled onto fruits and vegetables or in beverages.

[5] Industry sources have reported to the FDA that sugar-based Mexican-style candy recipes can contain as much as 15% chili, while salt-based products, e.g., some powdered snack mixes, can contain as much as 30% chili (Ref. 6).

[6] USDA's Handbook #8 gives a moisture content for hot chili peppers with seeds of 74%, and when dried (with seeds) of 12%. This equates to a concentration factor of about 6 from drying.

manufacturers could significantly reduce lead levels in their candy products by ensuring that their chili ingredients are sourced from suppliers that effectively wash the peppers before they are ground.

If the lead range data for the chili from washed peppers is adjusted for a 6-fold concentration effect, the corresponding lead levels in chili peppers would average about 40 ppb with a range of 4 to 190 ppb. Because TDS data on lead levels in raw green peppers indicate that lead is typically not detected on the peppers, we believe that the industry data on lead levels in chili suggest that substantial contamination of the peppers may be occurring at some point prior to the grinding operation, e.g., perhaps during open field drying, if the pepper is placed on the ground to dry. In addition to a washing operation prior to grinding, actions to control soil contamination of chili peppers during all stages of product's life, e.g., not placing the pepper in contact with the ground during "off the plant" drying, could also minimize lead levels in Mexican-style candy products.

We believe that Mexican-style candy manufacturers could obtain chili with 0.2 ppm or less lead content by sourcing chili made from effectively washed chili peppers, which were handled, e.g., dried, under good agricultural practices. Consequently, even for high-chili-content candy and powdered snack mix products, we believe that candy with appropriately sourced ingredients will not exceed 0.1 ppm lead.[7]

ii. Salt-Based Powdered Snack Products

Included in the 7 Mexican-style candy products tested by FDA that contained over 0.5 ppm lead were 3 powdered snack mix products that did not contain chili, but contained salt as their primary ingredient. Industry has reported to FDA that Mexican salt-based snack products can contain more than 50% salt (Ref. 6), and FDA has encountered powdered snack mix products consisting of only salt, citric acid and flavoring (the latter two ingredients are refined ingredients that are not likely to contain significant amounts of lead). The finding of elevated levels of lead in such products suggests that salt is a source of lead contamination in some imported powdered snack mix products. Since salt available for use as a food ingredient in Mexico is reported to contain lead ranges of 0.01-0.08 ppm for marine salt and 0.1-1.5 ppm for mined salt (Ref. 6) we believe that salt at the high end of the range for mined salt was used in formulating some powdered snack mix products resulting in the food containing avoidable lead contamination. We believe that if manufacturers source salt to minimize lead levels, finished, high-salt- content powdered snack mix products will not exceed 0.1 ppm lead.

iii. Tamarind Pulp

Tamarind pulp is a popular ingredient in many Mexican-style candy products. Industry information submitted to FDA states that tamarind pulp may be present at levels not exceeding 5% in sugar-based Mexican candies. (Ref. 6) Although FDA has encountered some tamarind candy products packed in poorly made lead glazed bowls from which very

[7] This is based upon the chili content of candy and powdered snack mix products not exceeding 15% and 30% respectively, as has been reported to us by the industry.

high levels of lead leached into the candy,[8] the industry information for 22 samples of tamarind pulp from Mexico showed an average lead concentration of 0.014 ppm, with a standard deviation of 0.005 ppm, and a range of 0.006 to 0.028 ppm. These data suggest that tamarind as an ingredient can be produced under good manufacturing practices such that it is not likely to be a significant source of elevated lead levels in Mexican-style candies.

d. Other Candy Ingredients and Other Types of Candy

FDA reviewed data on lead levels in other common candy ingredients and other types of candy. For example, peanuts are a common candy ingredient. During the period mid-1991 through 2002, FDA collected and analyzed 40 samples of dry roasted peanuts as components of market baskets in its TDS. FDA did not detect lead in 39 of the 40 samples. FDA detected a trace amount of lead, estimated at 17 ppb, in the remaining sample.

Other types of nuts are used as candy ingredients. For mixed nuts collected in the TDS during the period mid-1991 through 2002, FDA did not detect lead in 33 of 40 samples it analyzed. FDA detected trace levels of lead in 6 of the 40 samples with a mean lead level of 4 ppb, and detected 90 ppb lead in the remaining sample.

Raisins are used as candy ingredients. During the period mid-1991 through 2002, FDA collected and analyzed 40 samples of raisins as components of market baskets in its TDS. FDA did not detect lead in 20 of the 40 raisin samples. The other 20 samples contained trace levels, with a mean lead level of 9 ppb, and a maximum estimated value of 31 ppb.

FDA also considered data for caramel candy, a candy typically made from sugar, butter, cream, and sometimes other ingredients such as syrup and flour. During the period mid-1991 through 2002, FDA collected and analyzed 40 samples of caramel candy as components of market baskets in its TDS. FDA did not detect lead in 36 of the 40 caramel candy samples. FDA detected trace levels of lead in the other 4 samples, with a mean lead level of 2 ppb, and a maximum value of 30 ppb.

Having considered data on common candy ingredients and other types of candy (besides sugar-based, chocolate and Mexican-style candy) FDA is not aware of any reason, e.g., ingredient considerations, why other types of candy cannot achieve lead levels of 0.1 ppm or less as we similarly found for sugar-based, chocolate and Mexican-style candies. Accordingly FDA believes that other types of candy besides sugar-based, chocolate and Mexican-style candies can also achieve lead levels of 0.1 ppm or less.

V. Health Protection Considerations

[8] The regulatory status of bowls of this type is not addressed in FDA's 2005 guidance on lead levels in candy and powdered snack mix products because it is addressed under FDA's Compliance Policy Guide 7117.07 entitled "Pottery (Ceramics); Imported and Domestic - Lead Contamination."

FDA has estimated the potential exposure of small children from the candy products with lead levels no higher than we anticipate to be present in candy produced when we issue the 0.1 ppm guidance level and has concluded that the lead in such candy products would not constitute a health hazard.

We used a modeling technique known as Monte Carlo simulation to estimate the mean and 90th percentile daily intake of lead per small child that would likely result if manufactures produced candy with these anticipated lead levels.[9] We then compared these lead intake levels to FDA's provisional total tolerable intake level (PTTIL) for lead by small children of 6 micrograms per day. (Ref. 1) The simulations incorporated data on lead concentration data from FDA's TDS and from industry, and food consumption data from the 1994-98 CSFII.

The PTTIL is the total daily lead intake from all sources that provides a reasonable margin of protection against the known adverse effects of lead. An estimate of lead intake from a respective type of candy that is low relative to the PTTIL indicates that the candy would not pose a significant risk for adverse health effects from lead exposure.

a. Sugar-Based Candy

For worst case lead levels we would anticipate to occur in sugar-based candy, FDA used the lead distribution data for suckers from the mid-1991 through 2002 TDS. As noted above, the lead distribution data for the 40 samples of suckers had a mean of 4 ppb and a standard deviation of 9 ppb. For consumption of sugar-based candy, FDA based its estimate on the most relevant food codes reported in the 1994-96, 1998 CSFII, i.e., hard candy and butterscotch candy.

The mean and 90th percentile lead intake estimates for sugar-based candy using these inputs were 0.04 and 0.09 micrograms per day for males and females 1-3 years of age, and 0.04 and 0.08 micrograms per day for males and females 4-6 years of age, respectively. (Ref. 7) These lead intake estimates likely represent a worst case scenario because some of the lead data for suckers was obtained during a time period when the FCC specification for lead in sugar was higher than the current value, i.e., 0.5 ppm rather than 0.1 ppm. Because of the lower current specification for lead in sugar, FDA believes that it is possible that the current lead distribution for sugar-based candy may have shifted to lower levels than those used to generate this simulation. Nonetheless, as these lead

---

[9] Monte Carlo simulations (Rubinstein, 1981) can be used to evaluate models in which one or more inputs (in this case, food intakes and lead levels in food) can be defined by a distribution of values. A Monte Carlo simulation takes a random value from the distribution of possible values for the input, uses that value in calculating the outcome of the model, stores the result, and then repeats the procedure a determined number of times (iterations) using new random values of the input taken from the distribution for each iteration. The resulting output from this procedure (e.g., lead intakes) is a range of possible outcomes for the model. A probability distribution function can be prepared from the range and can be used to estimate intakes (typically mean and/or 90th percentile) of substances in the diet.

intake estimates are well below the PTTIL of 6 micrograms per day, FDA believes that sugar-based candies would not pose a significant risk to small children for adverse health effects from lead exposure if sugar-based candies contain the lead levels we would anticipate when we issue the 0.1 ppm guidance level for lead in candy.

b. Chocolate Candy and Other Non-Mexican-Style Candy

For milk chocolate, FDA performed two lead intake calculations using a Monte Carlo simulation. (Ref. 7) One calculation used the lead distribution data for milk chocolate from the 1991-2002 results from the TDS and the other calculation used lead distribution data submitted by the industry. As noted above, the lead distribution data for the 40 TDS samples of milk chocolate had a mean of 25 ppb and a standard deviation of 18 ppb, while the lead distribution data for the 137 industry samples of milk chocolate had a mean of 28 ppb and a standard deviation of 22 ppb. For both milk chocolate calculations FDA used consumption data for milk chocolate from the 1994-96, 1998 CFSII.

The mean and 90th percentile lead intake estimates for milk chocolate using these inputs were 0.25 and 0.52 micrograms per day for males and females 1-3 years of age, respectively, using the TDS data, and 0.29 and 0.60 micrograms per day for males and females 1-3 years of age, respectively, using the industry data. For males and females 4-6 years of age, the mean and 90th percentile lead intake estimates for milk chocolate using these inputs were 0.34 and 0.72 micrograms per day, and 0.38 and 0.82 micrograms per day using the TDS and industry data, respectively.

The lead intake estimates calculated using the TDS and the industry data are consistent, and are well below the PTTIL of 6 micrograms per day. These estimates are based upon data that showed a small portion of milk chocolate samples with lead levels greater than 0.1 ppm. As noted above, FDA believes that, if milk chocolate manufacturers source their raw materials appropriately (which we anticipate will happen when we issue the 0.1 ppm guidance level for lead in candy), their finished products will contain less than 0.1 ppm lead. This would result in slightly lower lead intake levels from milk chocolate than those we estimated. Thus, FDA believes that milk chocolate would not pose a significant risk to small children for adverse health effects from lead exposure if milk chocolate contains the lead levels we would anticipate when we issue the 0.1 ppm guidance level for lead in candy.

For the intake simulation for dark chocolate (Ref. 7), FDA used the lead distribution data for dark chocolate submitted by the industry. As noted above, the lead distribution data for the 226 industry samples of dark chocolate had a mean of 48 ppb and a standard deviation of 29 ppb. For the dark chocolate lead intake calculation, FDA used consumption data for dark chocolate from the 1994-96, 1998 CFSII.

The mean and 90th percentile lead intake estimates for dark chocolate using these inputs were 0.40 and 0.80 micrograms per day for males and females 1-3 years of age. For males and females 4-6 years of age the mean and 90th percentile lead intake estimates for dark chocolate using these inputs were 0.44 and 0.91 micrograms per day. These lead

intake estimates are well below the PTTIL of 6 micrograms per day. These estimates are based upon data that showed some dark chocolate samples with lead levels approaching and above 0.1 ppm. FDA anticipates that any dark chocolate manufacturers who market products likely to be consumed frequently by small children will source their raw materials accordingly and that lead intake levels for children who consume such products would be somewhat lower than those we estimated. FDA believes that dark chocolate products would not pose a significant risk to small children for adverse health effects from lead exposure if the dark chocolate contains the lead levels we would anticipate when we issue the 0.1 ppm guidance level for lead in candy.

FDA believes that lead intakes from other types of candy, excluding Mexican-style candy and powdered snack mix products, would likely be within the range of lead intakes bounded by sugar-based and milk chocolate candies, because common candy ingredients, e.g., peanuts, nuts, and raisins, do not appear to pose the potential to introduce lead into candy products at levels exceeding those in sugar-based and chocolate candy.

c. Mexican-Style Candy and Powdered Snack Mixes

i. With Chili as an Ingredient

Both hard sugar-based candies included in the intake estimate above, and soft sugar-based candies containing tamarind pulp are typical of Mexican-style candies that contain chili. For estimating lead intake from these candies, FDA assumed that chili would be present at 15% by weight in both sugar based soft and hard candies, that all the lead in the candy would be contributed by the chili ingredient, that in response to the new guidance Mexican candy manufacturers would source washed chili for their products intended for export to the U.S., and that the chili ingredient contained lead at the levels reported to us for washed chili by the industry, i.e., an average of 0.241 ppm lead (range 0.023 to 1.14 ppm) with a standard deviation of 0.173 ppm. FDA performed a lead intake calculation using a Monte Carlo simulation incorporating these assumptions regarding the chili content of soft and hard candies, and the lead content of chili, using consumption data from the 1994-96, 1998 CFSII for hard candy and for selected soft sugar-based candies (i.e., gum drops and soft fruit candy) that were considered to be suitable surrogates for Mexican-style candies. (Ref. 7)

The mean and 90th percentile lead intake estimates for Mexican-style candy using these inputs were 0.54 and 1.20 micrograms per day for males and females 1-3 years of age, and 0.60 and 1.31 micrograms per day for males and females 4-6 years of age, respectively. As these lead intake estimates are well below the PTTIL of 6 micrograms per day, FDA believes that Mexican-style candy would not pose a significant risk for adverse health effects from lead exposure if it contains the lead levels we would anticipate when we issue the 0.1 ppm guidance level for lead in candy.

ii. Salt-Based Powdered Snack Products

For powdered snack mix products, because the CFSII does not include any foods that are suitable surrogates for powdered snack mix products, FDA estimated lead intake for such products containing sugar, e.g., salt, sugar and chili, and such products not containing sugar, e.g., salt and flavoring or salt and chili, using consumption information for powdered snack mix products obtained from a short-term survey (Ref. 8). We performed a Monte Carlo simulation using the serving size and frequency information from the survey (Ref. 9) and assumed that the worst case lead content of the products would be 0.08 ppm. This level, 0.08 ppm, is the upper end of the reported lead range for marine salt in Mexico (Ref. 6), and salt is the principal ingredient in powdered snack mix products. FDA recognizes that chili can be present at levels up to 30% in powdered snack mix products, and can also be a source of lead in these products. However, FDA believes that manufacturers who use chili in their products are likely to source chili containing less than the average reported lead level for washed chili and are also likely to source salt at the lower end of the reported lead range for marine salt. Therefore, the 0.08 ppm assumption is reasonable for firms that minimize the lead content of their ingredients.

We estimated for children 2-5 years of age, a 90^{th} percentile lead intake for sugar containing powdered snack mix products of about 2.3 micrograms per day, and a 90^{th} percentile lead intake for non-sugar containing powdered snack mix products of about 0.9 micrograms per day. As these lead intake estimates are well below the PTTIL of 6 micrograms per day, FDA believes that Mexican powdered snack mix products would not pose a significant risk for adverse health effects to small children from lead exposure if they contain the lead levels we would anticipate when we issue the 0.1 ppm guidance level for lead in candy.

iii. With Tamarind as an Ingredient

As noted above, based upon low concentrations of lead found in tamarind pulp samples, FDA believes that tamarind is not likely to be a significant source of elevated lead levels in Mexican-style candies when the tamarind ingredient or finished candy is produced under good manufacturing practices and not held or packed in lead glazed bowls that may leach elevated levels of lead into the pulp or candy. Because of the low levels of lead found in the sample of tamarind pulp cited above, as opposed to the much higher lead levels that have been reported or found in some chili and salt samples, FDA did not calculate separate lead intake estimates for Mexican-style candy products that contain tamarind, but not chili or salt. We believe that the significant sources of addressable lead exposure from Mexican-style candy products are the chili and salt ingredients in some products.

VI. References

1. Federal Register, Vol. 58, pg. 33860, June 21, 1993.
2. Federal Register, Vol. 44, pg. 51233, August 31, 1979.

3. Bolger, P. Michael, Yess, Norma J., Gunderson, Ellis L., Troxell, Terry C., and Carrington, Clark D., "Identification and reduction of sources of dietary lead in the United States," *Food Additives and Contaminants*, Vol. 13, pg. 53, 1996.
4. "A characterization of lead in chocolate products," provided by the Chocolate Manufactures Association, March 2005.
5. FDA data on analysis of Mexican candy products for lead, October 2000 to February 2004.
6. "A characterization of lead in Mexican candy," Provided by the National Confectioner's Association, March 2005.
7. FDA estimate "Lead intake from candies," prepared 4/21/05.
8. FDA Memorandum, "Analysis of Informal Survey of Consumption of Spicy Mix Products by CLPPB," Michael E. Kashtock, December 13, 2004.
9. FDA Memorandum, "Lead in Spicy Chili Mix Candy," Clark Carrington, April 22, 2005.