AN ABSTRACT OF THE THESIS OF

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Childhood lead poisoning is one of the most common preventable pediatric health problems in the United States. Fetuses, neonates, and young children are particularly sensitive to adverse health effects associated with lead exposure due to children's hand to mouth activities, their greater ability to absorb lead, and their vulnerable developing nervous systems. Lead poisoning can result in decreased intelligence, impaired neurobehavioral development, stunted physical growth, hearing and kidney problems, juvenile delinquency, and a propensity to commit criminal acts.

Well-documented past sources of lead exposures in children are from leaded paint, leaded gasoline, lead-contaminated soils and dust, leaded soldered cans and water pipes, and lead-glazed pottery. Certain Mexican folk remedies such as *Alarcon*, *Azarcon*, *Coral,* and *Greta* have also been shown to contain dangerous levels of lead (Greta, for example, is composed of approximately 99% lead oxide). Recently, several studies have shown that a number of brands of candies from Mexico contain unsafe levels of lead.

This study was initiated to assess whether lead-tainted imported candies are available in Mexican markets (tiendas) in Oregon. Hood River, Marion, Benton, and Multnomah counties were selected in this study based on the percent of the population that is Hispanic and their proximity to Oregon State University (OSU). This study was funded by the College of Health and Human Sciences at OSU with additional support from Benton and Multnomah County Health Departments.

Imported Mexican candies were collected and sent to a certified laboratory (accredited by the American Industrial Hygiene Association (AIHA) and the Environmental Laboratory Accreditation Program (ELLAP) in association with EPA National Lead Laboratory Accreditation Program (NLLAP)) for lead analysis. A limited number of candy wrappers and candy sticks were also tested for lead. Results show that 45% of the candies tested had detectable levels of lead and of those 87.5% exceed the new U.S. Food and Drug Administration (FDA) guideline of 0.1 ppm. Results also show that samples with detectable lead levels vary by county (28-82%). In addition, between 19% and 75% of the candies had excessive lead content by main ingredient in the candy (e.g., tamarind, chili, salt). When total micrograms of lead in a serving of candy is calculated (for samples with detectable lead), between 33 to 86% exceed FDA's Provisional Total Tolerable Intake of Lead (PTTIL) of 6 µg lead per day by 10 to 41 times. Moreover, 50% of one brand tested had detectable lead content. This brand also had 100% of its wrappers and 94% of its sticks with excessive lead content. Statistical tests did not show a relationship between lead content of candies and ingredients. Statistical tests did not show a relationship between lead content of candies and lead content of wrappers for one brand tested. However, a negatively correlated relationship was found between lead in the candies and lead in the sticks for one brand tested. Use of the Environmental Protection Agency's (EPA) Integrated Exposure/Uptake Biokinetic Model (IEUBK) showed increases in mean Blood Lead Levels (BLL) for all age groups with two age groups exceeding the U.S. Centers for Disease Control and Prevention (CDC) definition of an elevated childhood BLL ($\geq$ 10 µg/dL). Results of this study will be shared with key federal and state health and regulatory agencies for appropriate follow-up action.

Lead in Imported Candy from Mexico in Four Counties in Oregon

by
Elisabeth D. Maxwell

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CONTRIBUTION OF AUTHORS

Dr. Cathy Neumann initiated this project as a part of her own research. She has been the guiding force behind the publishing endeavor and has been key to the project's completion.

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Introduction

Background

Lead (Pb) is an ancient metal and its toxicity has been recognized for millennia. At high doses, lead poisoning can affect target organs such as the liver and kidneys, as well as the vascular, cardiovascular, immunological, reproductive, gastrointestinal, endocrine, and central nervous systems (Nriagu, 1983). Lead is a human neurotoxin with no known threshold, and even low blood lead levels are known to cause adverse health effects in children (Bellinger et al., 1991; Bellinger et al., 1992; Canfield et al., 2003; Fergusson et al., 1997; Kordas et al., 2006; Landrigan, 2000; Lanphear et al., 2000; Lanphear et al., 2005; Pocock et al., 1994; Tong et al., 1996). Fetuses, neonates, and young children with developing nervous systems are particularly sensitive to adverse health effects associated with lead exposure. Lead poisoning can result in decreased intelligence, impaired neurobehavioral development, stunted physical growth, hearing and kidney problems, juvenile delinquency, and a propensity to commit criminal acts (Bellinger et al., 1991; Bellinger et al., 1992; Dietrich et al., 2001; Fels et al., 1998; Needleman et al., 1996; Needleman et al., 2002; Otto et al., 1993; Sanin et al., 2001).

The current definition of an elevated blood lead concentration (called blood lead level, BLL) established by the U.S. Centers for Disease Control and Prevention (CDC) for children and adolescents is 10 micrograms per deciliter (μg/dL). This level has been reduced four times over the past 30 years due to increasing evidence that BLLs $\geq$ 10 μg/dL are associated with adverse effects such as lowered intelligence. The U.S. Food and Drug Administration (FDA) recommend that children under age six consume less than 6.0 μg lead daily from all food sources (Carrington et al., 1992).

Despite a drop in the prevalence of lead poisoning among children in the United States, the CDC estimates that approximately 434,000 preschool children are at risk for exposure to harmful lead levels (Meyer, 2003). In Oregon, an estimated 2,000 to 5,000 children have BLLs $\geq$ 10 μg/dL (personal communication, Rick Leiker, Manager, Oregon's Childhood Lead Poisoning Prevention Program, 2006).

Childhood lead poisoning is one of the most common preventable pediatric health problems in the United States (Needleman, 2004). Most children with elevated BLLs are exposed to lead through contaminated house dust from lead-based paint in old, urban homes (Lanphear et al., 1995; Lanphear et al., 1997). Several million children currently live in lead contaminated (pre-1950s) residential homes (Mushak et al., 1990). These same children, unfortunately, often possess many of the risk factors that exacerbate the manifestations of lead toxicity, such as low socioeconomic status, low iron, and diminished calcium intake (Mahaffey, 1995; Tong et al., 2000).

Historically, other sources of lead exposures in children have been from leaded gasoline, lead-contaminated soils and dust, leaded soldered cans and water pipes, and lead-glazed pottery. Certain Mexican folk remedies such as A*larcon*, A*zarcon*, *Coral,* and G*reta* have also been shown to contain dangerous levels of lead (Agency for Toxic Substances and Disease Registry, 2006). Recently, new sources of lead exposure in children have emerged such as imported crayons, jewelry, chocolates, and imported candies from Mexico (Dahiya et al., 2005; FDA, 2006; Lynch et al., 2000; Neumann et al., 1996; U.S. Consumer Protection and Safety Commission, 2006). As recently as April of 2006, Pepsi settled a lawsuit with the state of California over labels on bottles manufactured in Mexico that contained up to 45% lead (Associated Press, 2006). There was also a recall of Dagoba chocolate, an Oregon company, in March of 2006 because of high levels of lead in several of their products (FDA, 2006).

Problem Statement

Since the early 1990s, FDA and the California Department of Health Services (CA DHS) have shown that certain Mexican candies contain hazardous levels of lead (CA DHS, 2005; FDA, 1995; FDA, 2001). There have been numerous newspaper reports, including an extensive investigation by the *Orange County Register* (OCR) and the FDA regarding lead contaminated candies imported from Mexico (US FDA, 2005; OCR, 2004). To date there has only been one published paper on lead-contaminated candies imported from Mexico. This study by Lynch et al. (2000) was initiated after a young child in Oklahoma was diagnosed with a BLL of 35 μg/dL during a routine screening for lead. During the investigation, lead was determined to be in the paint and soil in the child's home environment. The child's father implemented the recommended lead reduction protocols to minimize any further lead exposures to the child. However, at a subsequent visit the child's BLL was diagnosed at 48 μg/dL. Further investigation implicated tamarind suckers that the child had been eating regularly as a source of lead poisoning. Lead was confirmed in one of the tamarind suckers with XRF testing and laboratory analysis. This case prompted the researchers to initiate a study of the lead content in these types of tamarind suckers. The researchers found that over 50% of the candy samples tested exceeded the FDA Level of Concern (0.50 mg/kg) for lead in tamarind candy. The wrappers were also tested for lead content and found to contain high levels of lead concentration, ranging from 459 mg/kg to 27,125 mg/kg, suggesting possible leaching from lead-based inks onto the candies.

The focus of the present study is to investigate whether imported lead-contaminated candy from Mexico is available in the four selected counties in Oregon. There are large Hispanic populations in several counties in Oregon including the four selected for this research: Hood River (24.3%), Multnomah (23.9%), Marion (16.4%), and Benton (7.7%). According to officials at Oregon Department of Agriculture (OR DOA), Oregon Department of Health Service's (OR DHS) Oregon Children's Lead Poisoning Prevention Program (OCLPPP) and Oregon State University's (OSU) Western Regional Lead Training Center (WRLTC) there is an urgent need to test candy and wrappers imported from Mexico that are sold at local Mexican markets (tiendas) in Oregon counties with large Hispanic populations (Personal communications: Ron MacKay, Food Safety Program Director, OR DOA, 2006; Rick Leiker, Manager OCLPPP, 2006; Ann Kimerling, Director WRLTC, 2006).

Research Objectives and Research Questions

The objectives of the current study were to: (1) select local Mexican markets (tiendas) using OR DOA grocery store inspection lists in selected counties to collect Mexican candies for testing; (2) send candy samples to a certified laboratory (accredited by the American Industrial Hygiene Association (AIHA) and the

Environmental Laboratory Accreditation Program (ELLAP) in association with EPA National Lead Laboratory Accreditation Program (NLLAP)), to be analyzed for lead content; (3) calculate total lead content in each candy based on weight and total lead ingestion using different estimates of candies consumed; (4) use biokinetic modeling to assess blood lead levels associated with consumption of lead-tainted candies imported from Mexico; and (5) alert involved state health and regulatory agencies about possible health risks from imported candies for appropriate follow up. The research questions for this study are the following:

1. Are there elevated levels of lead in Mexican candy, candy wrappers, and candy sticks from the four selected counties?
2. If so, are lead levels of public health concern?
3. Is there a relationship between candy ingredients (tamarind, chili, sugar, etc.) and lead content?
4. Is there a relationship between lead levels in wrappers or sticks and lead levels in candies?
5. Testing one specific brand of candy that is widely available, do lead levels vary in individual candies, wrappers, and sticks?

Significance of the Study

This study is significant because there has been very little research on the availability of lead-tainted Mexican candies in Oregon. OR DHS had funding to test a few pieces of imported candies from Mexico a few years ago, but the small sample size did not provide allow generalizability of the results to the rest of Oregon (personal communication, Rick Leiker, Manager OCLPPP, 2005). In addition, it is well-known that there is no safe threshold for lead exposure (Bellinger et al., 1991; Bellinger et al., 1992; Canfield et al., 2003; Fergusson et al., 1997; Kordas et al., 2006; Landrigan, 2000; Lanphear et al., 2000; Lanphear et al., 2005; Pocock et al., 1994; Tong et al., 1996). Moreover, the percentage of the U.S. population who are Hispanic is steadily growing and is expected to reach 24% by the year 2050 (U.S. Census Bureau, 2004). The results of this study will be shared with health and regulatory agencies in Oregon for appropriate follow-up. This study will also inform future studies regarding the availability of lead-contaminated candies in Oregon.

Limitations of the Study

The results of this study are based on data generated from four counties in Oregon and may not be generalizeable to other counties, states, or countries. In addition, a limited number of candy wrappers and sticks were analyzed. Moreover, lead can vary within a particular candy or particular brand. Furthermore, composite sampling and digestion may yield different results.

Definitions

Blood Lead Level (BLL): the amount of measurable lead in blood, usually expressed in micrograms per deciliter (μg/dL)

Provisional Total Tolerable Intake for Lead (PTTIL): FDA's recommended total intake of lead for children younger than 6 years is 6μg/day.

μg: microgram

Abbreviations/Acronyms

AIHA:	American Industrial Hygiene Association
APHA:	American Public Health Association
ATSDR:	Agency for Toxic Substances & Disease Registry, Department of Health and Human Services
CPSC:	United States Consumer Product Safety Commission
EDL:	Electrodeless discharge lamp
EHC:	Environmental Health Coalition
ELLAP:	Environmental Laboratory Accreditation Program
IEUBK:	Integrated Exposure/Uptake Biokinetic Model
NIOSH:	The National Institute for Occupational Safety and Health, part of the United States Centers for Disease Control and Prevention
NLLAP:	National Lead Laboratory Accreditation Program
NMDH:	New Mexico Department of Health
OCLPPP:	Oregon Children's Lead Poisoning Prevention Program
OCR:	Orange County Register newspaper
OR DHS:	Oregon Department of Health Services
OR DOA:	Oregon Department of Agriculture
OSU:	Oregon State University
US CDC:	United States Centers for Disease Control and Prevention
US EPA:	United Stated Environmental Protection Agency
US FDA:	United States Food and Drug Administration
WA DOH:	Washington Department of Health
WRLTC:	Western Regional Lead Training Center
XRF:	X-ray fluorescence

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CHAPTER 2

Lead-Tainted Candies Imported from Mexico and Other Lead Contaminated Consumer Products

History

Lead is an ancient metal known to have been used by human beings from 6500 B.C. for beads, glass-making, cosmetics, and enamel pottery (Wedeen, 1984). Lead is also mentioned in the Bible in the book of Jeremiah (Nriagu, 1983). Hippocrates appears to have been the first person to document a case of lead colic in a worker which was attributed to lead poisoning (Castellino et al., 1995). In the 2nd century B.C., Nikander, a Greek physician, described the symptoms of lead poisoning following lead ingestion (Needleman, 2004). Lead has been implicated as one factor in the demise of the Roman Empire as it was widely used in food as a sweetener (Castellino et al., 1995). Lead colic was a problem in Europe throughout the Middle Ages (Needlman, 2004). In the modern era, lead has been used in glassmaking, metal roofs, and inks (Castellino et al., 1995).

Occupational lead exposure is a significant source for adults. In 1978, an estimated one million workers were exposed to lead (National Institute for Occupational Safety and Health, 1978). Okun et al. (2004) found that there has been a general reduction in blood lead levels across various occupations since 1978, with the exclusion of the construction industry. There are many industries where lead exposure in workers can occur including: lead smelting, lead refining, battery manufacture, steel welding/cutting, construction, rubber/plastic production, printing, firing ranges, and radiator repair (NIOSH, 1978). There is also the potential for a worker's family to be exposed to lead through contaminated clothes and on personal items kept at work and brought home.

One of the more disturbing historical uses of lead has been as a medicine. Paracelsus, the father of modern toxicology, noted lead to be a good remedy for diarrhea (Nriagu, 1983). As early as 2000 B.C., China and India used lead as medicine (Castellino et al., 1995). In 1500 B.C., the Egyptians used it as medicine for constipation, diarrhea, to stop hemorrhages, and for abortions (Castellino et al., 1995). In the last few centuries, lead has been used medicinally in many countries including:

Mexico to treat diarrhea; in England for diarrhea, burns, and gonorrhea; in France for cancer treatment; and in Italy for eye drops and vaginal wash (Castellino et al., 1995).

Sources of Lead

Lead poisoning in children was first documented in Australia in the latter part of the 19th century and the early part of the 20th century by Dr. J. Lockhart Gibson (Gibson, 2005). Dr. Gibson was also the first to hypothesize that the children he was treating for lead poisoning were being sickened by lead paint in their homes. During this same period, sporadic cases of lead poisoning in children were also documented in the U.S. (Rosner et al., 2005). However, in the U.S. through the 1920's, public health officials were preoccupied with other childhood diseases and did not consider lead poisoning to be an important childhood disease (Rosner et al., 2005). At the same time, the lead paint industry knew about the potential for lead poisoning from lead paints, and according to Rosner et al. (2005) deliberately kept this hidden from the public. One of the strategies that the lead paint industry utilized to keep the dangers of lead hidden was to fund most of the research on lead toxicity in the U.S. from the 1920's and through the 1970's (Silbergeld, 1997). It was not until the 1950's that the United States paint industry agreed to remove lead from paint, and not until 1978 that the U.S. Consumer Product Safety Commission banned paint containing more than 0.06% lead for residential use (Rosner et al., 2005; Silbergeld, 1997). However, this did not stop the leaded paint that was already in existence from poisoning children. The CDC estimates that leaded paints are still the most common source of lead exposure in children (US Department of HHS, 2006).

Lead was added to gasoline as an anti-knock agent starting in the 1920s. This source also significantly contributed to children's body burdens of lead (US Dept of HHS, 2006). Lead was also used in the soldering of cans for food (US Dept of HHS, 2006). However, these uses of lead were banned in the U.S. starting in 1973 with leaded gasoline and in 1991 for food cans (EPA, 1996; Nadakavukaren, 2006). Over the years, other sources of lead in imported medicines and cosmetic products, including ones from Mexico, have been reported (Table 2.1).

Adverse Health Effects

At high doses, lead has been associated with a variety of health problems in children. At BLLs exceeding 125 μg/dL, death can occur from encephalopathy (US Dept of HHS, 2006). In early 2006, a four year old child died in the U.S. after swallowing a necklace that was highly contaminated with lead (US CPSC, 2006). Early signs of lead toxicity are abdominal and joint pain (Needleman, 2004). Children may also show signs of central nervous system involvement such as headaches, behavioral changes, convulsions, and loss of consciousness (Needleman, 2004).

As a result of the ban on lead in gasoline and soldered food cans, Pirkle et al., (1994) showed that the mean and prevalence of BLLs in people from 1 to 74 years of age declined over 70%. As some of the more notorious sources of lead exposure were eliminated or reduced, researchers became interested in the health consequences of low dose lead exposures to children.

Infants and young children are more vulnerable to the harmful effects of lead than adults because of their incomplete blood-brain barrier and their ability to absorb a greater amount of lead than adults (US Dept of HHS, 2006). Preschool children who ingest lead absorb 40% of the lead into their bloodstreams, whereas adults absorb 10% of ingested lead into their bloodstreams (Nadakavukaren, 2006). Children are also more susceptible to lead due to their behaviors such as hand to mouth activities, mouthing toys and other items off the floor, and more time spent on and near the floor. These activities can bring children into contact with dust and soil (environmental lead), flaking lead paint, and other lead-contaminated items. An association was reported between BLL's <20 μg/dL and anemia in children 1-5 years of age (Schwartz et al., 1990). Sanin et al., (2001) showed correlations between BLL at one month of age, maternal bone lead level, and slow weight gain. Several studies have shown associations between umbilical cord lead concentrations, low birth length, and low head circumference (Ballew et al., 1999; Hernandez-Avila et al., 2002). Positive associations have also been found between lead exposure and dental caries in children (Campbell et al., 2000; Gemmel et al., 2002; Moss et al., 1999).

Low-dose lead exposure has been shown to be associated with various cognitive deficits and behavioral issues in young children. Thomson et al. (1989)

showed a dose-response relationship between blood lead levels and behavior ratings using a behavior scale from parents and teachers in Edinburgh, Scotland. No evidence of a threshold for adverse effects from lead exposure was found in this study. Bellinger et al. (1991) reported an association between children with umbilical cord BLLs between 10 and 25 μg/dL and cognitive deficits through 24 months of age, especially for visual-spatial and visual-motor integration skills. A follow-up study of this same group of children showed an association between the lead exposure and deficits in intellectual and academic performance at ten years of age (Bellinger et al., 1992). Tong et al. (1996) found a correlation between antenatal and postnatal blood lead concentrations and later IQ deficits in an Australian population of children 11-13 years of age who lived near a lead smelter.

Needleman et al. (1996) found that adjudicated delinquents were four times more likely to have elevated lead burdens as measured by bone lead concentrations. Several other studies have found correlations between lead exposure and aggressive and delinquent behaviors (Dietrich et al., 2001; Needleman et al., 2002). In addition, children living in poverty and having social disadvantages (parents' occupational prestige, quality of the home environment, and mother's intelligence quotient) may be more sensitive to the adverse effects of lead exposure (Tong et al., 2000).

A study by Lanphear et al. (2000) using data from the Third National Health and Nutrition Examination Study (NHANES III) found that for every 1 μg/dL increase in BLLs, there was a decrease in mean scores for arithmetic, reading, nonverbal reasoning, and short-term memory. In an international pooled analysis of seven studies, evidence was found of intellectual deficits among children who had maximal blood lead levels of less than 7.5 μg/dL (Lanphear et al., 2005). Importantly, cognitive deficits were shown in a population of children whose BLLs were < 5 μg/dL, suggesting that there is no threshold (i.e. safe dose) (Landrigan, 2000).

Another study on lead exposure and IQ reviewed 26 epidemiological studies from 1979 through the 1990's that examined BLLs or dentine lead and IQ in young children (Pocock et al., 1994). This study found that a typical doubling of the body lead burden was associated with loss of 1-2 IQ points. Canfield et al. (2003) found blood lead concentrations <10 μg/dL were associated with deceases in IQ from 4.6

points to 7.4 points at three and five years of age. This same study also showed greater IQ deficits at lower BLLs rather than higher BLLs. More recently, Kordas et al. (2006) studied a sample of Mexican first graders living near a metal foundry and found an association between BLLs as low as 10 μg/dL and decreases in cognitive performance. Chiodo et al. (2004) reported an association between BLLs as low as 3 μg/dL and decrements in attention, executive function, and visual-motor integration domains. Importantly, cognitive deficits associated with exposure to lead persist into adulthood (Fergusson et al., 1997).

Lead in Imported Candy from Mexico

A new source of exposure to lead in children has emerged in the form of imported candies from Mexico. United States Food and Drug Administration (FDA) has issued recalls and health alerts regarding Mexican candies based on high lead levels (Fig. 2.1). An investigation by the *Orange County Register* (OCR) found many candy brands imported from Mexico to have high lead levels (Table 2.2). To date there has only been one published report (located in preparation for the current study) analyzing lead levels in candies imported from Mexico. This study by Lynch et al. (2000) was initiated after a young child in Oklahoma was diagnosed with a BLL of 35 μg/dL at a routine screening for lead. During the investigation, lead was determined to be in the paint and soil in the child's home environment. The child's father implemented the recommended lead reduction protocol to minimize any further lead exposures to the child. However, at a subsequent visit the child's BLL was diagnosed at 48 μg/dL. Further investigation implicated tamarind suckers that the child had been eating regularly as a source of lead poisoning. Lead was confirmed in one of the tamarind suckers with XRF testing and laboratory analysis. This case prompted the researchers to initiate a study of the lead content in these types of tamarind suckers. The researchers found that over 50% of the candy samples tested exceeded FDA's Level of Concern (0.50 mg/kg) for lead in tamarind candy. The wrappers were also tested for lead content and found to contain high levels of lead concentration suggesting possible leaching from lead-based inks onto the candies.

Lynch et al. (2000) used the U.S. Environmental Protection Agency's (EPA) Integrated Exposure Uptake Biokinetic (IEUBK) model was used to predict possible increases in mean BLLs for children following consumption of lead-contaminated candies. A 43% increase in the geometric mean BLL for children ages 6-84 months was predicted from consuming one candy per day using the mean lead concentration in one product. An 84% increase was found using the mean lead concentration of the second product in the study. Moreover, this model predicted a 5-fold increase in the prevalence of BLLs ≥ 10 μg/dL for the first product and an 11-fold increase for the second product.

Regulatory Issues

The U.S. federal government has utilized several strategies in its efforts to protect children from the harmful effects of lead poisoning. FDA has issued many recalls and health alerts regarding various brands of Mexican candies imported to the U.S. (Figure 2.1). The CDC has lowered the definition of an elevated BLL four times with the last reduction in 1991 to $\geq$10 μg/dL (CDC, 1991). Lead is on the FDA's list of poisonous and deleterious substances which was established to control contaminants in food (US Dept of HHS, 2006).

As shown in Figure 2.1, FDA has issued the following recalls of candies imported from Mexico due to elevated lead: in 1993 *Picarindo*, a tamarind fruit candy; in 1998 *Jarrita Chonita Tejocote* candy; and in 2004 *Chaca Chaca* candy (FDA, 1993; FDA 1998; FDA 2004a). FDA also notified the public about voluntary recalls by the manufacturer of candies imported from Mexico due to elevated lead, as in 2001 with *Dulmex Tamarind* candy (FDA, 2001b). In 1995 FDA issued a guidance letter setting the lead level in candies imported from Mexico at 0.5 ppm (FDA, 1995). On March 25, 2004, FDA issued a letter to manufacturers, importers and distributors of Mexican candy products to reduce lead in their products (FDA, 2004b). In this same year, FDA issued a statement advising the public not to eat candy from Mexico which contained chili and/or tamarind (FDA, 2004c). In 2005 FDA issued an import alert in regard to four different candies with elevated lead (FDA, 2005a). In December of 2005, FDA issued a new guidance for lead in candy (0.1 ppm or less) (FDA, 2005b;

FDA, 2005c). In response to this, the American Academy of Pediatricians sent a letter to FDA recommending that it enforce the new guidance (0.1 ppm or less), uphold its Provisional Total Tolerable Intake for Lead (PTTIL) of 6 μg/day of lead in children, and publicly acknowledge that there is no safe level of lead (FDA, 2006b).

In 2001, FDA issued a press release alerting the public to possible health risks associated with *Dulmex* brand *Bolirindo* candy tamarind lollipops from Mexico, after California Department of Health Services (CA DHS) found at least three cases in young children where eating imported candy from Mexico may have contributed to elevated BLLs. The Department of Health Service's (DHS) Oregon Childhood Lead Poisoning Prevention Program (OCLPPP) tested additional tamarind candies from Mexico and found that they also contained hazardous levels of lead (personal communication, Rick Leiker, OCLPPP, DHS, 2006). In May of 2001, Washington (WA) Department of Health (DOH) and OR DHS issued similar public health advisories warning about unsafe levels of lead in tamarind candies. In 2004, OCLPPP tested Mexican candies with chili and found they also had high lead levels (personal communication, Rick Leiker, Manager, OCLPPP, DHS, 2006).

Recently, CA DHS issued another advisory warning consumers not to eat *Chaca Chaca*, an imported chili-based candy from Mexico that was recalled by FDA in 2004 due to harmful levels of lead (CA DHS, 2005; FDA, 2004a). This candy was found to contain 0.3-0.4 μg of lead per gram of product. The large size of this candy (30 grams) could result in a young child ingesting nearly twice the recommended FDA PTTIL of 6 μg of lead each day. Likewise, Lynch et al. (2000) reported high enough lead concentrations in two kinds of tamarind candy lollipops imported from Mexico that a child consuming one-quarter to one-half of either of these suckers would exceed the maximum FDA tolerable intake for lead.

Not surprisingly, there have been five documented cases of elevated BLLs (>10 μg/dL) in young Hispanic children in the U.S. from eating candy and other items imported from Mexico (Courtney et al., 2002). Of approximately 1,000 cases of elevated BLLs among children that were reported to CA DHS during May 2001 - January 2002, candy produced in Mexico was identified as a possible exposure source in approximately 150 cases (Editorial Note, in Courtney et al., 2002).

Lead has also been detected in candy wrappers imported from Mexico. The use of lead-based inks for labeling candy wrappers has been a regulatory issue for over ten years (FDA, 2002). While the U.S. and European Union abandoned the use of metal-based inks in food wrappers some time ago, lead and chromium (Cr) have been found in imported candy wrappers from Mexico and the Philippines (personal communication, Richard Jacobs, FDA, Alameda, CA, 2005).

The Consumer Product Safety Commission (CPSC) also regulates lead-tainted products. In December of 1998, CPSC issued the Codification of Guidance Policy on Lead in Consumer Products (CPSC, 1998). This Guidance directed Mexican candy manufacturers to eliminate lead in their products and test for lead periodically in their products. In July of 2004, CPSC sent a letter to US candy importers and to Mexican candy producers warning them of the lead-tainted candies and advising of possible recalls and legal actions resulting from importing such items (CPSC, 2004).

California has been at the forefront of dealing with lead in candy imported from Mexico due to its close proximity to Mexico and its large Hispanic population. CA DHS has released many public health advisories in the last decade warning of high lead levels in various candies: including *Picarindo, Brinquitos, Rebanaditas, Mango Elotes,* and *Chaca Chaca* (OCR, 2004). There have been numerous newspaper reports, including an extensive investigation by the OCR in California regarding lead contaminated candies imported from Mexico (OCR, 2004). As shown in Table 2.1 numerous brands of Mexican candy were found to have elevated levels of lead. Figure 2.2 is an example of one of two posters (one in English and one in Spanish) that the OCR produced to highlight to the public brands which had high lead levels. As a result of the OCR investigation, a bill (AB 121) that requires CA DHS to test for lead content in imported candies was introduced into the CA legislature and was signed by Governor Schwarzenegger on October 7, 2005 (CA DHS, 2005). Moreover, CA state government officials and public health advocates spent two years negotiating with Mexican candy manufacturers to reduce lead from their products (OCR, 2006). An agreement was reached in June of 2006 with the top three Mexican candy manufacturers, including two that are subsidiaries of US companies (Mars and Hershey). The manufacturers agreed to annual audits of their manufacturing sites and chili suppliers, lead testing of their products, a cash payment of nearly one million dollars to reduce lead in the Mexican candy industry, and to pay legal fees. This agreement also allows smaller companies to sign on at later dates.

Conclusion

Lead is a human neurotoxin to which children are particularly sensitive. While many sources of lead have been reduced and eliminated, new sources continually emerge. The overt toxic properties of lead in humans have been known for hundreds of years. Evidence of the insidious effects of low-dose lead exposure on children's cognitive abilities has been accumulating for the last twenty years. Unfortunately, the ubiquitous nature of lead from natural and anthropogenic sources results in some body burden in children. Therefore, it is imperative to eliminate lead sources which can be easily and readily abated, such as in food products.

One of the lessons the United States has learned from its experience with Mexico is that lead-contaminated products can make their way into a country through many channels, some within government control and some outside of it. Large shipments of candies can be imported into the U.S. subject to periodic FDA inspection. Other routes that may escape inspection by FDA include motor vehicles or foot traffic or in personal luggage. States may need to implement their own testing programs to ensure the safety of candy and other products.

California has recently demonstrated to other states that a coalition of government officials and public health advocates can successfully negotiate to resolve the issue of lead-tainted candy from Mexico. Other states are using different tactics to protect children from lead-contaminated candies from Mexico. In 2005, the New Mexico Department of Health (NMDH) launched a public health campaign to educate families about the potential dangers of imported candies from Mexico (NMDH, 2005). NMDH distributed 1000 Toxic Treats posters (Figure 2.1) to public elementary schools in an effort to educate children and parents. In California, middle school children have taken on several projects from collecting signature petitions to sending examples of lead-contaminated candies to the governor, in an effort to educate the public and urge more stringent enforcement of lead standards (OCR, 2004). Moreover, other organizations such as the Environmental Health Coalition (EHC) and the American Public Health Association (APHA) have publicly urged FDA to stringently enforce lead guidelines to protect children from the harmful effects of lead (APHA, 2006; EHC, 2006).

There is evidence that FDA has repeatedly tried to gain firm control of the issue of lead-tainted candies from Mexico through recalls, health alerts, letters to the industry (manufacturers, distributors, and importers) and the recent reduction in the recommended allowable lead level in these candies (0.1 ppm). However, as the American Academy of Pediatricians pointed out in its letter of this year, regular enforcement of the new level and public acknowledgement that there is no safe level of lead may be the best ways to protect the most vulnerable among us. Children cannot protect themselves from lead-tainted candy. Moreover, children who may already bear other burdens associated with poverty are more vulnerable to the pernicious affects of lead. More regulatory and enforcement action is warranted, given recent findings that there is no safe level of exposure.

Table 2.1 Possible Lead Containing Home Remedies and Cosmetics
Source: OCLPPP, 1997 (http://oregon.gov/DHS/ph/lead/docs/homeremedies.pdf)

Region of Origin	Name	Appearance	Use	Miscellaneous
Mexico	Azarcon (rueda, Coral, maria luisa, Alarcon, Liga, luiga)	Red/orange powder	Empacho (vomiting, colic, apathy, lethargy)	95% lead
Mexico	Greta	Yellow powder	See above.	97% lead
Mexico and Central America	Albayalde or albayaidle	White powder	See above.	93% lead
Dominican Republic	Litargirio	Yellow or peach-colored powder	Deodorant, foot fungicide, burn treatment	79% lead. Sold in 2-inch by 3-inch clear packets
Laos (Hmong)	Pay-loo-ah (also known as pejluam or PeLua)	Red powder	Given for rash or fever	90% lead
Asia/India	Ghasard	Brown powder	Given as an aid to digestion	May be given as a daily tonic, 2% lead
Asia/India	Bali goli	Round, flat, black bean	Given to treat stomachache	Dissolved in 'gripe' water
Asia/India	Kandu	Red powder	Given to treat stomachache	
Asia/India	Deshi Dewa		Fertility pill	12% lead
Africa, Asia, India, Pakistan, Middle East	Kohl (Alkohl, Tiro Surma, Saott)	Black powder	Cosmetic, astringent for eye injuries, skin infections	Teething powder. Used on umbilical stump of newborn child
Asia	Chuifong tokuwan		?	
China	Hai Ge Fen (also known as Sai Mei An)	Clamshell powder	Given to treat stomachache, ulcers or mouth sores	Brewed in tea. ("Used to cool inner heat" that causes illnesses)
China	Ju Hua (formally known as Xyoo Fa).	Tea, solution, pills.	Given to treat headache, fever, dizziness, & stomachache.	Available in different forms.
China	Litharge (also known as Mi Tuo Seng)	Green/red powder	Available in different forms	Contains lead oxide.
China	Cordyceps		Herbal medicine treatment for hypertension, diabetes, bleeding	
China	Ba Bow Sen		Hyperactivity & nightmares in children.	
India/Pakistan	Kushta		Diseases of the heart, brain, liver, stomach.	Also used as an aphrodisiac & tonic.
India, Pakistan, Sri Lanka, Burma, Bhutan, Mongolia,	Unknown (Ayurvedic)		Metal-mineral tonic, slows development.	1.38-72,990 µg/g per capsule.

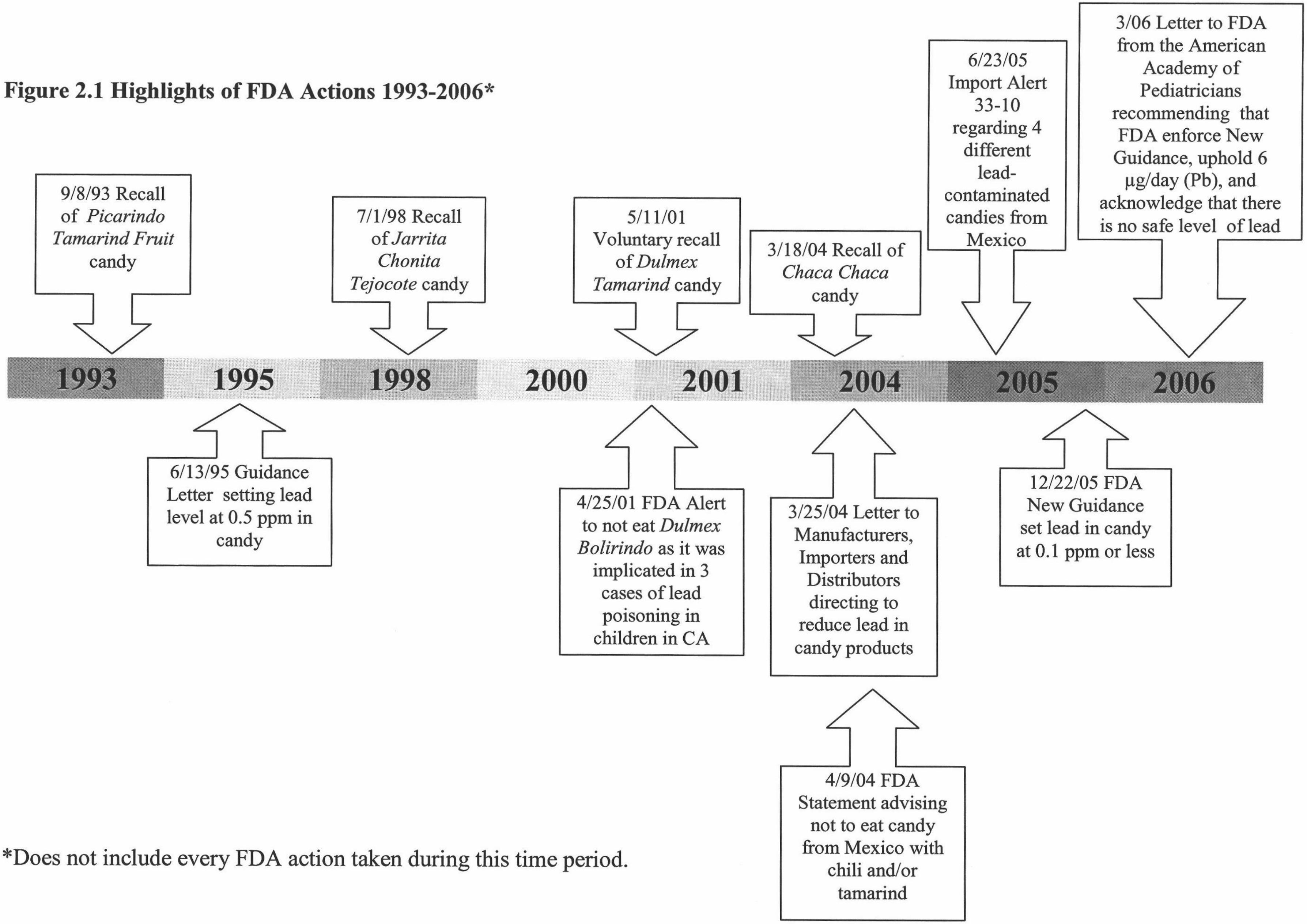
Tibet				
Middle East	Anzroot		Gastroenteritis	
Middle East	Cebagin		Teething powder	51% lead
Middle East	Henna		Hair and skin dye	
Oman, Saudi Arabia, India	Bint al dahab, bint or bent dahab		Diarrhea, colic, constipation, general neonatal use.	98% lead
Saudi Arabia	Bokhoor (and noqd)		Wood and lead sulfide burned on charcoal to produce pleasant fumes and calm infants.	
Saudi Arabia	Al Murrah		Colic, stomachaches, diarrhea.	
Saudi Arabia	Farouk & Santrinj		Teething powder	

(Compiled by the NSW Lead Reference Centre, 1997 from "Lead is a Silent Hazard," 1994, pp. 154-156 and associated articles in the medical literature)

Table 2.2 Mexican and Other Candies with Elevated Lead levels in California OCR, 2004 (http://www.ocregister.com/investigations/2004/lead/index.shtml)

Agrimiel lollipop	Paleta Ricorindo
Aldama Obleas con Cajeta	Paleton con Chile "Teco"
Arco Iris Tamarind	Pelon Pelo Rico
Arcor Frutilla	Pica Limon
Astro Pop	Picante Peanuts (El Senor)
Baby Lucas	Pico Diana
Beso Ardiente	Pina Loca
Besos Ricos	Pinta Rojo (wrapper tested at 15,000ppm)
Betamex Dulce de Tamarindo	Pollito Asado
Bolirindo	Pulpa Rago Chamoy
Bomba Chile	Pulparindo
Brinquitos	Pulpitas
Cachitos	Rollito de Coco
Canel's Gum	Rollito de Tamarindo
Chaca Chaca	Saladulces Hola, Sabor Agridulce
Chaca Chaca Rielito	Saladulces Hola, Sabor Naranja
Chiclorindo	Serpentinas (1 wrapper tested 15,000ppm)
Chupirul	Simpsons con Super Chile
Coronado Cajeta	Storck Eucalyptus Menthol
Crayon Pulpa Sabor Mango	Super Lucas Hot 'n Spicy Chili Mix
De La Rosa Paleta	Tablarindo
Diablitos Tamarindin	Tama Roca
Dulce de Tamarindo La Colonial	Taman Zela con Chile
Duvalin	Tiramindo con Sabor de lo Lindo
Enchiladas Luxus	Tutsi Pop
Hershey's	Uy Uy Uy
Indy Hormigas	Vagabundo con Chile
Lickem Pop	Vagabundo Extremo
Limon 7	Vero Chupadedo
Lucas Acidito	Vero Elotes
Lucas Dulce de Tamarindo	Vero Mango
Lucas Limon	Vero Manita
Lucas Pelucas	Vero Palerindas
Margarita Dulce de Tamarindo	Vero Pica Gomas
Melon con Chile	Vero Pinaleta
Milkoko	Vero Pinaleta
Montes Damy	Vero Super Palerindas
Montes Tomy	Vero Super Rebanaditas

Figure 2.1 Highlights of FDA Actions 1993-2006*



*Does not include every FDA action taken during this time period.

Figure 2.2 Toxic Treats
OCR, 2004
(http://www.ocregister.com/investigations/2004/lead/pdf/poster_english.pdf)

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CHAPTER 3

Lead in Imported Candy from Mexico in Four Counties in Oregon

Introduction

Lead (Pb) is an ancient metal and its toxicity to humans was recognized almost from the time humans started using metals for tools. Inorganic and organic lead exert the same detrimental effects on humans (International Agency for Research on Cancer, 2004). Lead poisoning can affect both adults and children. In children, the mostly preventable effects of lead exposure can be quite devastating, both physically and cognitively (US Department of Health and Human Services, 2006). At high doses, lead has been associated with a variety of health problems in children, including death from encephalopathy (US Dept of HHS, 2006). Signs of lead toxicity are abdominal and joint pain, and central nervous system involvement such as headaches, behavioral changes, convulsions and loss of consciousness (Needleman, 2004). Lead has no known threshold, and even low blood lead levels are known to cause adverse health effects in children (Bellinger et al., 1991; Bellinger et al., 1992; Canfield et al., 2003; Fergusson et al., 1997; Kordas et al., 2006; Landrigan, 2000; Lanphear et al., 2000; Lanphear et al., 2005; Pocock et al., 1994; Tong et al., 1996). Fetuses, neonates, and young children with developing nervous systems are particularly sensitive to adverse health effects associated with lead exposure. Lead poisoning can result in decreased intelligence, impaired neurobehavioral development, stunted physical growth, hearing and kidney problems, juvenile delinquency, and a propensity to commit criminal acts (Bellinger et al., 1991; Bellinger et al., 1992; Dietrich et al., 2001; Fels et al., 1998; Needleman et al., 1996; Needleman et al., 2002; Otto et al., 1993; Sanin et al., 2001).

The current definition of an elevated blood lead level (BLL) established by the U.S. Centers for Disease Control and Prevention (CDC) for children and adolescents is $\geq$ 10 micrograms per deciliter (µg/dL). The CDC BLL has been reduced four times over the past 30 years due to increasing evidence indicating that BLLs $\geq$ 10 µg/dL are associated with adverse effects such as lowered intelligence.

The Third National Health and Nutrition Examination Study (NHANES III) 1999-2000 estimated that 434,000 children or 2.2% of children aged 1 to 5 years had BLLs $\geq$ 10 µg/dL (Meyer, et al., 2003). The goal of eliminating BLLs > 25 µg/dL by the year 2000 was not achieved, and a significant number of children are still at risk of suffering adverse health effects from lead exposure. Oregon is considered a low-prevalence state for BLLs (personal communication, David Lew, State of Oregon Epidemiologist, 2006). Although all Oregon Medicaid-eligible children are required to be assessed for lead poisoning risk before age 1 and 2 years, medical provider compliance is inconsistent. The estimated percentage of state Medicaid-eligible children under age 6 who had a blood lead test in 2005 was estimated to be 6.2%. In 2004, of Medicaid-eligible children tested in Oregon, 1.1% had an initial BLL $\geq$ 9 µg/dL. In 2005, the percentage was 1.25% with an initial BLL $\geq$ 9 µg/dL. In both years, there did not appear to be a significant difference between males and females. For Medicaid-eligible children identified as Hispanic, 0.8% had an initial blood lead test of $\geq$ 9 µg/dL in 2004 and 0.7% had an initial blood lead test of $\geq$ 9 µg/dL in 2005. In Oregon, current data do not show that Hispanic children have higher BLLs than children of other ethnicities or races. However, it should be noted that there are some issues with how ethnicity is reported for these children and it is possible that children with unknown ethnic status may be Hispanic, leading to some under-reporting.

Historically, sources of lead exposures in children have been from leaded gasoline, lead-contaminated soils and dust, leaded soldered cans and water pipes, and lead-glazed pottery (Agency for Toxic Substances and Disease Registry, 2006). Certain Mexican folk remedies such as *Alarcon*, *Azarcon*, *Coral* and *Greta* have also been shown to contain dangerous levels of lead (ATSDR, 2006). Recently, some emerging sources of lead exposure in children have been highlighted in the mainstream media and academic research such as imported crayons, jewelry, and chocolates (Dahiya et al., 2005; U.S. Food and Drug Administration, 2006; Lynch et al., 2000; Neumann et al., 1996; U.S. Consumer Protection and Safety Commission, 2006). In addition, Pepsi settled a lawsuit with the state of California in April 2006 over labels on bottles manufactured in Mexico that contained up to 45% lead (Associated Press, 2006). There was also a recall of Dagoba chocolate, an Oregon company, in March of 2006 because of high levels of lead in several of their products (FDA, 2006).

Since the early 1990s, the U.S. Food and Drug Administration (FDA), the California Department of Health Services (CA DHS), and independent investigators (Lynch et al., 2000) have shown that certain Mexican candies contain elevated levels of lead (Orange County Register, 2004). FDA recommends that children under age six consume less than 6.0 μg lead daily from all food sources (Carrington et al., 1992). In December of 2005, FDA issued a guideline entitled, "Lead in candy likely to be consumed frequently by small children: recommended maximum level and enforcement policy." This guideline reduced the maximum allowable amount of lead in imported candies from 0.5 ppm to 0.1 ppm (FDA, 2005).

California has been at the forefront of dealing with lead in candy imported from Mexico due to its close proximity and large Hispanic population. CA DHS has released many public health advisories in the last decade warning of high lead levels in various candies. There have been numerous newspaper reports, including an extensive investigation by the *Orange County Register* (OCR) in California regarding lead contaminated candies imported from Mexico (OCR, 2004). Figure 3.1 is an example of posters that the OCR produced to highlight several of the brands that had high lead levels. This poster is also available in Spanish. Table 3.1 lists some of the brands of imported candies from Mexico that were found to have elevated lead levels during the OCR investigation.

As a result of the OCR's investigation, a bill (AB 121) that requires CA DHS to test for lead content in imported candies was signed by the governor of California on 10/7/05 (CA DHS, 2005). Moreover, government officials and public health advocates in California spent two years negotiating with Mexican candy manufacturers to reduce or eliminate lead from their products (OCR, 2006). An agreement was reached in June of 2006 with the top three Mexican candy manufacturers, including two that are owned by US companies (Mars and Hershey). The manufacturers agreed to annual audits of their manufacturing facilities and chili suppliers, lead testing, and a cash payment of nearly one million dollars to reduce lead in the Mexican candy industry and to pay legal fees. In addition, this agreement allows smaller companies, not already included, to sign on at later dates.

In Oregon, there have been small-scale efforts to test imported candies from Mexico (personal communication, Rick Leiker, 2005). The Oregon Department of Human Services (OR DHS) regularly posts health alerts on their website stemming from other State or Federal investigations, as well as voluntary recalls (OR DHS, 2006). In addition, the OR DHS Childhood Lead Poisoning Prevention Program (OCLPPP) actively supported the current study with data assistance and field expertise.

The current study was initiated to assess whether lead-tainted imported candies are available in Mexican markets (tiendas) in Oregon, and if so to determine whether the levels posed a public health concern. A preliminary assessment of the relationship between lead content of the candies and candy ingredients was also done. The relationship between lead levels in wrappers or stems and lead levels in candies was assessed, as well. Lastly, the lead content in candies, wrappers and sticks in one specific brand of candy were assessed.

Methods

County Selection

The current study reports on lead in candy products imported from Mexico in four counties in Oregon with large Hispanic populations (based on 2000 census data). The four counties were: Hood River (24.3% Hispanic), Multnomah (23.9% Hispanic), Marion County (16.4% Hispanic), and Benton (5.3%) (Figure 3.2). Note: Malheur County has a large Hispanic population of 25% but due to its long distance from OSU, this county was not selected.

Tienda Selection

Imported candy samples imported from Mexico were purchased from local retail stores (small Mexican markets called *tiendas*) in the selected counties. A list of retail stores in each county was provided by the Oregon Department of Agriculture (OR DOA) and used to identify tiendas. Information was logged specifying the exact location where the candy was bought, the manufacturer, and the lot number of the candy (when available). The candy and wrapper were placed in individual sealed plastic bags and labeled. Pictures were taken of the wrapper and candy, and all other identifiers on the package were recorded. Retail stores were photographed when possible and described. Each sample was also assigned an identifying code. Figure 3.2 depicts a process flowchart of the actions taken in regard to the candy for this study.

Analytic Methods

NVL Laboratories in Seattle, Washington was contracted to analyze candy and wrappers using Graphite Furnace Atomic Absorption Spectrophotometry (EPA Method 7010). This laboratory is accredited by the American Industrial Hygiene Association (AIHA) and the Environmental Laboratory Accreditation Program (ELAP) in association with EPA National Lead Laboratory Accreditation Program (NLLAP), and it tested candy and other samples for Washington Department of Health (WA DOH) (personal communication, Jennifer Livingston, Childhood Lead Surveillance Program Manager, 2005). X-Ray fluorescence (XRF) and lead test swabs (Lead Check) were used to pre-screen wrapper samples for lead prior to shipping to NVL for laboratory analysis.

The first process used to analyze the candy samples in this study 'Microwave Assisted Acid Digestions of Candy Products for Lead (Pb) Analysis' is designed to mimic extraction using conventional heating with nitric acid (HNO_3), in accordance with EPA method 3051A. This method is an alternative technique of expediting the extraction process of analytes (lead) from bulk materials (candy, wrapper, or stem) at elevated temperature with the use of microwave energy. Digests produced by this method were used for analysis by graphite furnace atomic absorption spectrophotometry (GFAAS). Quality control was maintained during the laboratory processes by periodically (every 20 samples) bringing a duplicate sample through the entire analysis process.

A representative sample (candy, wrapper, or stick) of up to 0.5 gram (g) was extracted and/or dissolved in 50 milliliters (mL) polypropylene vessel to be digested in the microwave. 5 ± 0.1 mL concentrated nitric acid was added to the vessel in a fume hood. After cooling, the vessel contents were diluted to volume, centrifuged, filtered or allowed to settle prior to analysis by the appropriate determinative method.

The GFAAS method (EPA 7010) was then used for digestion and a representative of each candy sample was placed in the graphite tube in a furnace, evaporated to dryness, charred and atomized. Radiation from a given excited element, in this case lead, is passed through the vapor containing ground-state atoms of that element. The intensity of the transmitted radiation decreases in proportion to the amount of the ground-state element in the vapor. The lead atoms were then placed in the beam of radiation by increasing the temperature of the furnace, causing the injected specimen to be volatilized. A monochromator isolated the characteristic radiation from a electrodeless discharge lamp (EDL), and a photosensitive device measured the attenuated transmitted radiation. The laboratory results were reported in milligrams per kilogram (mg/kg). This value was calculated with the following formula:

C= concentration in extract (μg/mL)

D= dilution factor

S= sample weight in grams

V= diluted sample volume in mL

Sample Concentration = (C) (V) (D)/(S)

The Reporting Limit (RL) was < 0.08 mg/kg (80 μg/kg). The RL is essentially a detection limit. The laboratory test was unable to detect lead below this level.

Statistical Analysis

Chi-square calculations for lead values by ingredient were analyzed. The relationship between three ingredients (chili, tamarind and salt) which have been associated with high lead levels in Mexican candies in past FDA investigations and the corresponding lead levels were calculated using Chi-square. The lead levels were placed into categories in the rows by whether each was below the RL; between 80-120 μg/kg; between 130-200 μg/kg; or between 210-2200 μg/kg. The row categories are divided according to the lab results in lead levels.

Spearman's Rank Correlation Coefficient was used to attempt to determine a relationship between lead in the candy for one brand tested and lead in the wrappers or sticks. This non-parametric statistical test is appropriate because the data are not normally distributed and there are outliers.

Calculation of Total Lead

To assess the total micrograms of lead in a serving of candy, the following equation was used:

Micrograms (μg) lead per candy= μg/g (gram) lead candy X wt of candy (g)*

**Note: μg/kg is converted to μg/g via the equation: μg/kg X 1kg/1000g*

For example candy sample 3AK weighed 28.35 g and had 2200 μg/kg of lead: 2200 μg/kg x 1kg/1000g= 2.2 μg/g x 28.35 g = 62.37 μg lead in the entire piece of candy. For all of the candy samples collected, a serving size listed on the label is one individual piece of candy. FDA's Provisional Total Tolerable Intake for Lead (PTTIL) in children younger than 6 years is 6μg/day (d) (Carrington et al., 1992). It is important to consider that FDA's 6 μg/d tolerable intake limit includes lead from all sources including candy, Mexican pottery, home remedies, food, water, and dust from leaded paint.

IEUBK Model

The Integrated Exposure/Uptake Biokinetic (IEUBK) model from the U.S. Environmental Protection Agency (EPA) was used to estimate BLLs in children exposed to lead-contaminated media using four interrelated modules: exposure, uptake, biokinetic, and variability distribution (User's Guide for IEUBK, 2002). The exposure component is an estimated intake rate for the quantities of lead inhaled or ingested from environmental media (User's Guide for IEUBK, 2002). The media addressed are soil, house dust, drinking water, air, and food. The uptake component models how lead intake is transferred to the blood. Since only a fraction of lead (bioavailability) is absorbed into the systemic circulation, the model utilizes different bioavailabilities from the different media. The biokinetic component is a mathematical depiction of the movement of absorbed lead throughout the body over time by physical or biochemical processes. The variability component addresses the differences that can occur among exposed children.

The IEUBK model was used to evaluate the possible effects on BLLs in children 11 months and younger up to 84 months of age from consuming lead-contaminated candies imported from Mexico. The model utilizes assumptions about background levels of lead in air, water, diet, soil, and dust. It also makes assumptions about the bioavailability of lead in each media type. For this analysis, the default levels were used, as shown below. Since consumption of lead-tainted candies imported from Mexico is not part of any background level, the alternate exposure pathway was used to enter the data for lead in candy. The bioavailability was set at the recommended 50%. Two total lead levels (10 μg and 40 μg) were used with the IEUBK model. Ten micrograms was chosen because it is the mean amount of total lead in the one brand tested for lead in candy, wrappers, and sticks. Forty micrograms was chosen as it was the maximum total lead found in the candy of the same brand. Both daily and weekly consumptions were entered into the model.

Results

Table 3.2 shows the percentages of candy samples by lead content. Lead levels in candies ranged from <80 μg/kg to 2200μg/kg. Fifty-five percent (%) (78/142) were below the RL (<80 μg/kg) for lead. Twenty-three samples (16.1%) had lead levels ranging from 80 to 130 μg/kg. Twenty-eight of the candies (19.7%) had lead levels between 140 and 260 μg/kg. Eight samples (5.6%) had between 300 and 460 μg/kg of lead. Two candies (1.4%) had lead levels between 540 and 650 μg/kg. Three samples (2.1%) had lead levels from 1000 μg/kg to 2200 μg/kg.

As shown below, the percentages of Mexican candies above the RL by individual county varied in this study.

- ❖ Benton County: 82% (14/17)
- ❖ Marion County: 50% (7/14)
- ❖ Multnomah County: 44% (32/72)
- ❖ Hood River County: 28% (11/39)

Benton County had the highest percentage of candies that exceeded the RL, followed by Marion County. Multnomah and Hood River counties, while having a lower percentage of candies exceeding the RL, had the highest lead content in a single candy, 2200 μg/kg and 2000 μg/kg, respectively.

Table 3.3 shows the Mexican candy samples over the RL of 80 μg/kg. Fifty-six out of sixty-four of the candy samples (87.5%) met or exceeded FDA's guideline for candy of 100 µg lead. The lead content in these samples ranged from 80 µg/kg to 2200 µg/kg lead. The county where each candy sample was purchased is also depicted in Table 3.3. Ninety-four percent (30/32) of the candy samples collected from Multnomah County tiendas met or exceeded the FDA limit of 100 µg lead. In Hood River County, 100% (11/11) of the samples were equal to or greater than 100 µg lead (FDA's limit). Both Benton (10/14) and Marion County (5/7) samples had 71% at or above 100 µg lead. This table also includes a description of the candy and the main ingredients of each candy sample. The main ingredients were located on the wrappers and only the first two or three ingredients are listed. In many cases, a candy that appeared to be flavored with actual fruit, such as tamarind, was found to be artificially flavored.

Table 3.4 depicts Chi-square calculations for lead values by ingredient. The degrees of freedom for the 4 x 3 table are 6. The Chi-square is 1.688. For significance at the 0.05 level, the Chi-square should be ≥ 12.59. The p-value is 0.946. Therefore, the distribution is not significant. No specific ingredient was found to be associated with lead levels in the candies.

As shown in Table 3.5, as the number of lead-tainted candies consumed increases, so do the number of brands that exceed FDA's PTTIL of 6 µg lead/day. This is a theoretical consumption calculation. It is simply the calculation of the amount of lead that would be ingested by a child if one, two or four pieces of a specific candy were consumed. For example, when the calculation is performed for one piece of candy consumed, 33% of the samples exceed the PTTIL and range from 6 to 62.4 µg lead (10-fold over FDA's PTTIL). With two candies consumed, 63% of the samples exceed the PTTIL and range from 6.4 to 124.7 µg lead (21 times over FDA's PTTIL). With four pieces is consumed, 86% of the samples exceed the PTTIL and the range is 7.2 to 249.5 µg lead (41 times over FDA's PTTIL).

Table 3.6 shows lead in candy, wrapper and stick of one brand of Mexican imported candy. This brand, which was found in other reports to have high levels of lead candy, is packaged in a bright yellow wrapper that contains a tamarind roll containing chili and salt (OCR, 2004). The mean for lead in the candy sample (n=18) is 118 µg/kg ± 236 µg/kg with a range from <80 µg/kg up to 1000 µg/kg. Calculating total lead in the entire piece of candy ranged from 3 to 40 μg with a mean of 10 μg ± 12. The lead in the wrappers ranged from 90 μg/kg to 5900 μg/kg with a mean of 2064 μg/kg ± 1652 μg/kg. The lead in the sticks ranged from <80 μg/kg to 96,000 μg/kg with a mean of 14,359 μg/kg ± 25,913 μg/kg. Seven of the sticks had lead content over 1000 μg/kg and four had lead content over 10,000 μg/kg.

Figures 3.3 and 3.4 depict scatterplots of the data points for lead in candy and lead in the wrappers for the one brand tested, and for lead in candy and lead in the sticks, also for this same brand. The outliers in each figure are shown in the top portion of the plot. There does not appear to be a clear and defined linear relationship. Spearman's Rank Correlation Coefficient was computed for these variables. Between lead in the candy and lead in the wrappers, no significant relationship was found (ρ = 0.049; p-value = 0.848). However, between lead in the candy and lead in the sticks a negative correlation was found ((ρ = -0.495; p-value = 0.037). A negative correlation indicates that as y (lead in candy) decreases in magnitude, x (lead in the sticks) increases in magnitude. This test does not determine cause and effect, only that there is a relationship between the two variables.

Table 3.7 depicts the default values of media of EPA's Integrated Exposure/Uptake Biokinetic (IEUBK) model. Table 3.8 shows the results using these default values. The model predicted background or baseline geometric mean BLLs ranging from 3.8 μg/dL in the youngest children (0-11 mo.) to 2.5 μg/dL in the oldest children (72-84 mo.). Ten μg lead was chosen to use with the IEUBK model because it is the mean lead content for the single brand tested as shown in Table 3.6. When daily consumption of 10 μg lead in candy was calculated, BLLs ranging from 5.9 μg/dL (0-11 mo.) to 3.8 μg/dL (72-84 mo.) resulted which show increases ranging from 39% to 55% over baseline. Daily consumption of the maximum level in the one brand tested (40 μg) yielded BLL ranges from 11.2 μg/dL (0-11 mo.) to 7.1 μg/dL (72-84 mo.), resulting in BLL increases from 144% to 195% over the baseline. Weekly consumption of a 10 μg lead level in candy ranged from 4.1 μg/dL (0-11 mo.) to 2.7 μg/dL (72-84 mo.) representing a moderate increase (5 to 8%) over the baseline. Weekly consumption of a 40 μg lead level in candy ranged from 5.0 μg/dL (0-11 mo.) to 3.3 μg/dL (72-84 mo.) resulting in increases from 22% to 32% over the baseline.

Two age groups were calculated to exceed the elevated blood lead concentration for children and adolescents of 10µg/dL. Daily consumption of a candy with 40µg lead had BLLs of 11.2 µg/dL for children 0-11 months of age and 10.5 µg/dL for children 12-23 months of age.

Discussion

The data from this study suggests that imported candies from Mexico with unacceptable lead levels are widely available in the four selected counties in Oregon. Forty-five percent of the candies had lead above the RL (> 80 µg/kg). Of these, 87.5% exceeded FDA's guidance for industry in which it is recommended that lead in candy not exceed a maximum level of 0.1 ppm or 100 µg (FDA, 2005). Furthermore, three samples had lead levels in excess of 1000 µg/kg. When the results were reviewed by individual county, it was found that between 71% and 100% of the samples above the RL met or exceeded 100 µg/kg.

One of the objectives of this study was to review the percentages of candies above and below the RL by ingredient. FDA has reported on numerous occasions that Mexican candies may be tainted with lead because ingredients in the candies have been contaminated with lead (FDA, 2004). Two of the ingredients which have been the focus of FDA concern are chili powder and/or tamarind. In this study, Chi-square calculations did not provide evidence of where the lead originated from in these samples.

However, one very concerning issue that emerged from this study is the amount of lead that may be ingested as a result of eating one or more pieces of lead-contaminated candies imported from Mexico. As the number of lead-tainted candies consumed increases, so do the number of brands that exceed FDA's PTTIL of 6 µg lead/day. The range over the PTTIL was from 10 times to 41 times the PTTIL. It is important to remember that the PTTIL is supposed to be from all sources of lead a child might encounter, such as from soil, dust, paint, air, other food sources, etc. Therefore, it is extremely concerning that children may be ingesting from 10 to 41 times the PTTIL from a single source.

Another objective of this study was to compare the differences in lead levels between candy, wrapper, and stick of one brand of Mexican imported candy. This brand was selected because it has been implicated in other investigations as having concerning levels of lead (XRF testing also implicated the sticks of this brand). The lead in the candy sample ranged from below the RL up to 1000 μg/kg. The lead in the wrappers ranged from 90 μg/kg to 5900 μg/kg and in the sticks from below the RL to 96,000 μg/kg. The results for this small sample are varied as can be seen from the range of values. The standard deviations are also quite large, indicating a high degree of variability in lead content. This analysis is based on a sample size of eighteen candies. It is likely that were the sample size to be increased, the standard deviation might decrease to a more acceptable width.

Statistical analysis using Spearman's Rank Correlation Coefficient test did not determine a relationship between lead in the candy and lead in the wrappers for the one brand tested. However, a negative relationship was found between the lead in the candy and the lead in the sticks. Unfortunately, this test cannot determine causality between the two variables. It is still unknown how the lead contaminates the product. One possible explanation is that there is lead contamination in the food processing and in the stick manufacturing.

Though a directional relationship was not determined between the lead in the candies and lead in the sticks or wrappers, the amount of lead found in the wrappers and, especially the sticks, is highly concerning. It is unknown if the lead originates in the candy and then migrates to the wrappers or sticks, or if lead originates in the sticks or wrappers and then migrates to the candy, or if each item is already contaminated prior to assembly into the finished product. Some samples had very high levels of lead in the stick or wrapper, but a level of lead in the candy below the RL, perhaps indicating little or no lead migration to the candy. It is also unknown at this time if lead in the sticks can become bioavailable if the sticks are chewed on or exposed to the enzymes in saliva. It is well-know that small children tend to chew on non-nutritive substances and to explore the world by mouthing objects. It is quite likely that sticks such as the ones found in this study are being chewed on by small children.

EPA's Integrated Exposure/Uptake Biokinetic (IEUBK) model was used to predict geometric mean BLL increases. Both daily and weekly consumption scenarios were calculated using the mean and maximum total lead from the one brand tested (Table 3.6). All age groups were calculated to have increases in BLLs, some as much as a 195% increase in the youngest age group. Importantly, the two youngest age groups were calculated to exceed the elevated blood lead concentration for children and adolescents of 10μg/dL with daily consumption of a candy with 40μg lead.

This study has some limitations which may make it difficult to generalize the results to other counties, states, or countries. Even for the four counties included in this study, the percentages of candies which exceeded the RL varied between 28% to 82%. This may indicate some unknown differences between counties in what types of candies are stocked in tiendas. It may also indicate that there are differences in how tiendas were sampled for this study. For example, in Hood River there were only two tiendas listed in the ODA database, but in Multnomah county there were hundreds listed. Therefore, this study captured all of the tiendas in Hood River County, but only a small fraction of the ones in Multnomah County. There is also the possibility of sampling bias in how the candies were selected. In some tiendas, it was possible to sample one each of every type of candy sold. In other tiendas, decisions had to be made to select only certain candies because the selection was quite large.

Another limitation of this study is the small sample size for the one brand tested for lead in candy, wrappers, and sticks. There was a high degree of variability in the mean and standard deviations for candy, wrappers, and sticks. It is likely that were a larger sample size tested, at least 30, some of this variability might decrease to more acceptable widths. In addition, it has been reported that lead in candy products tends to be variable within the same candy and within the same lot and brand. Therefore, it is possible that lead content results may vary even within the same candy tested.

Conclusion/Recommendations

FDA has been aware for approximately the last twelve years that the issue of lead-tainted candies imported from Mexico has been a problem. FDA has issued import alerts, health advisories, and guidelines to try to gain firm control of this issue and to protect children from the insidious adverse effects of lead poisoning. However, this study suggests that candies imported from Mexico are still readily and widely available to vulnerable young children. Some of these same children may also bear burdens of poverty which make them more vulnerable to the harmful effects of lead exposure. Oregon's own BLL statistics indicate that children who should be screened for elevated BLLs are not. Moreover, due to how ubiquitous lead is in the natural environment and from anthropogenic sources, it is imperative to control lead exposures which can be easily prevented, such as from imported candies from Mexico.

The health consequences for young children of not controlling the exposures which can be controlled are dire enough to warrant immediate and effective measures. California has provided an effective example for how other states can tackle this issue. To eliminate lead in imported candies from Mexico, California has: enacted legislation; managed to negotiate an agreement with the manufacturers (with the threat of a lawsuit); and had active grassroots organizations urging protective measures for children. Other states should consider creating similar strategies to protect children from lead in imported candy from Mexico.

In addition, the lead levels in the sticks are high enough to warrant immediate investigation by FDA and/or CPSC. In the course of this study, other studies or FDA information was not found that document high lead levels in the sticks. As it is unknown if lead can become bioavailable to small children, either due to the manual crushing from chewing or from enzymes in saliva, further investigation and study are merited.

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Figure 3.1 Toxic Treats
OCR, 2004
(http://www.ocregister.com/investigations/2004/lead/pdf/poster_english.pdf)

Figure 3.2 Oregon Map of Study Area Depicted by County

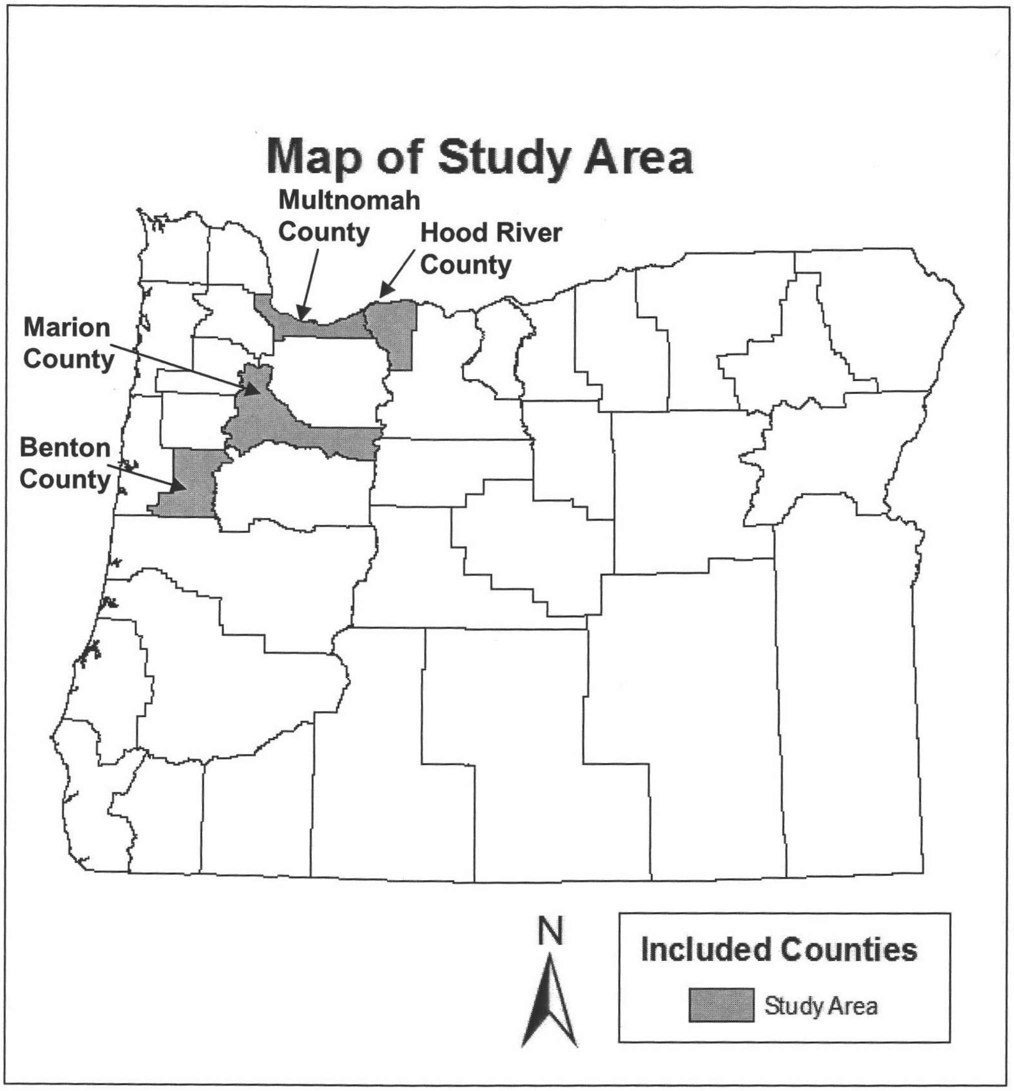

Table 3.1 Mexican and Other Candies with Elevated Lead levels in California OCR, 2004 (http://www.ocregister.com/investigations/2004/lead/index.shtml)

Agrimiel lollipop	Paleta Ricorindo
Aldama Obleas con Cajeta	Paleton con Chile "Teco"
Arco Iris Tamarind	Pelon Pelo Rico
Arcor Frutilla	Pica Limon
Astro Pop	Picante Peanuts (El Senor)
Baby Lucas	Pico Diana
Beso Ardiente	Pina Loca
Besos Ricos	Pinta Rojo (wrapper tested at 15,000ppm)
Betamex Dulce de Tamarindo	Pollito Asado
Bolirindo	Pulpa Rago Chamoy
Bomba Chile	Pulparindo
Brinquitos	Pulpitas
Cachitos	Rollito de Coco
Canel's Gum	Rollito de Tamarindo
Chaca Chaca	Saladulces Hola, Sabor Agridulce
Chaca Chaca Rielito	Saladulces Hola, Sabor Naranja
Chiclorindo	Serpentinas (1 wrapper tested 15,000ppm)
Chupirul	Simpsons con Super Chile
Coronado Cajeta	Storck Eucalyptus Menthol
Crayon Pulpa Sabor Mango	Super Lucas Hot 'n Spicy Chili Mix
De La Rosa Paleta	Tablarindo
Diablitos Tamarindin	Tama Roca
Dulce de Tamarindo La Colonial	Taman Zela con Chile
Duvalin	Tiramindo con Sabor de lo Lindo
Enchiladas Luxus	Tutsi Pop
Hershey's	Uy Uy Uy
Indy Hormigas	Vagabundo con Chile
Lickem Pop	Vagabundo Extremo
Limon 7	Vero Chupadedo
Lucas Acidito	Vero Elotes
Lucas Dulce de Tamarindo	Vero Mango
Lucas Limon	Vero Manita
Lucas Pelucas	Vero Palerindas
Margarita Dulce de Tamarindo	Vero Pica Gomas
Melon con Chile	Vero Pinaleta
Milkoko	Vero Pinaleta
Montes Damy	Vero Super Palerindas
Montes Tomy	Vero Super Rebanaditas

Figure 3.3 Flowchart of Candy Processes in this Study

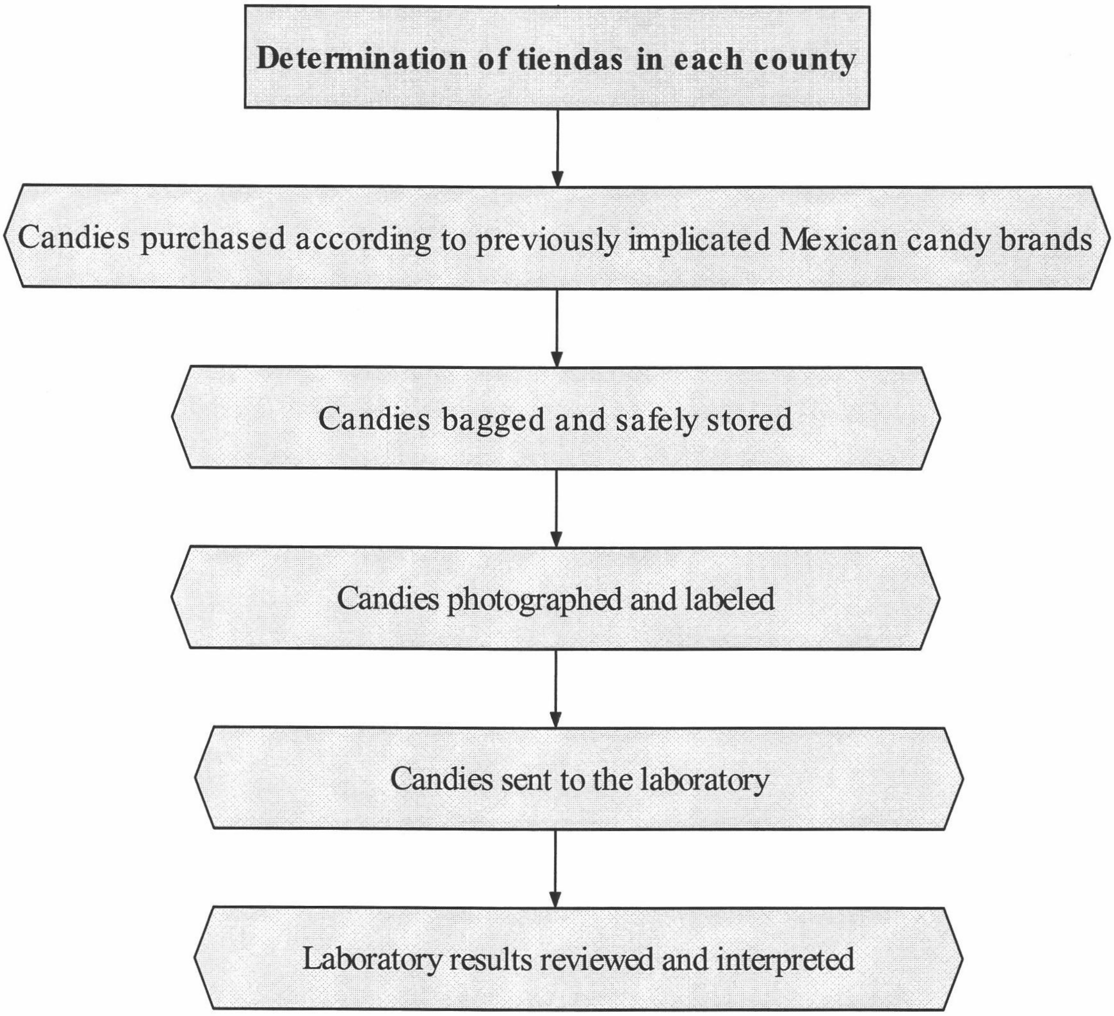

Table 3.2 Imported Mexican Candies in Oregon (n=142)

Individual Mexican Candies Tested (Percentage)	Lead Content (µg/kg)
78 (55%)	<80
23 (16.1%)	80-130
28 (19.7%)	140-260
8 (5.6%)	300-460
2 (1.4%)	540-650
3 (2.1%)	1000-2200

Table 3.3 Lead in Imported Mexican Candy in Four Counties in Oregon That Meet or Exceed the Reporting Limit of 80 µg/kg (n=64)

Sample Number	Lead (µg/kg)	Candy Description	Main Ingredients	County
3Ab	220†	Tamarind fruit roll coated with chili/salt	Tamarind, chili, salt	Multnomah
3Ac	540†	Lollipop with chili powder	Chili, salt	Multnomah
3Ae	200†	Fruit-flavored candy in a plastic tube	Chili, salt	Multnomah
3Af	190†	Candy with hazelnut and strawberry flavor	Sugar	Multnomah
3Ag	190†	Sweet/sour mango powder	Chili, salt	Multnomah
3Ai	140†	Cucumber-flavored lollipops with chili powder	Chili, salt	Multnomah
3Aj	110†	Chili coated lollipop	Chili, salt	Multnomah
3Ak	2200†	Tamarind-flavored candy in a tube	Chili, salt	Multnomah
3Al	310†	Tamarind/mango flavored candy coated spoon	Chili, salt	Multnomah
3An	240†	Mango-flavored lollipop with chili	Chili, salt	Multnomah

		powder		
3Ao	180†	Fruit-flavored soft candy	Chili, salt	Multnomah
3Ar	650†	Candy wrapped in tamale-like corn husk	Appears to have chili	Multnomah
3Ba	240†	Lollipop with a fruit gummi	Chocolate, marshmallow	Multnomah
3Be	200†	Fruit-flavored lollipop with chili powder for dipping	Chili, salt	Multnomah
3Bi	80	Mango-flavored powder	Chili, salt	Multnomah
3Bk	170†	Fruit-flavored candy in a tube	Chili, salt	Multnomah
3Bl	180†	Fruit-flavored lollipop	Chili, salt	Multnomah
3Bm	80	Tamarind fruit roll coated with chili/salt	Tamarind, chili, salt	Multnomah
3Bo	300†	Vanilla/hazelnut flavored candy	Sugar	Multnomah
3Ca	140†	Lollipop with a fruit gummi	Chocolate, marshmallow	Multnomah
3Cg	230†	Tamarind-flavored soft candy in a tube	Chili, salt	Multnomah
3Ch	170†	Tamarind pulp in a clear packet	Tamarind, chili, salt	Multnomah
3Ci	110†	Mango-flavored lollipop	Chili	Multnomah
3Cp	210†	Lollipop with a fruit gummi	Chocolate, marshmallow	Multnomah
3Da	300†	Lollipop with a fruit gummi	Chocolate, marshmallow	Multnomah
3Db	160†	Tamarind fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Multnomah
3Dc	100†	Mango-flavored fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Multnomah
3Di	180†	Hot/salty powder	Chili, salt	Multnomah
3Dj	110†	Strawberry-	Sugar	Multnomah

		flavored hard candy		
3Dk	130†	Roasted chicken-shaped lollipop	Chili, salt	Multnomah
3Dn	360†	Dried mango	Mango, chili	Multnomah
3Dr	180†	Chocolate bar	Chocolate	Multnomah
4Ac	250†	Loose in bulk jar: appears coated with chili	Unknown	Hood River
4Ag	110†	Lemon-lime powder	Salt	Hood River
4Al	180†	Fruit-flavored soft candy	Sugar	Hood River
4Ao	2000†	Sweet/sour fruit powder	Chili, salt	Hood River
4At	300†	Watermelon-flavored hard lollipop	Chili	Hood River
4Bb	460†	Lollipop with a fruit gummi	Chocolate, marshmallow	Hood River
4Bf	190†	Strawberry/vanilla flavored soft candy	Sugar	Hood River
4Bj	400†	Fruit-flavored hard lollipop	Chili, salt	Hood River
4Bo	220†	Mango-flavored hard lollipop	Chili	Hood River
4Bp	1000†	Tamarind fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Hood River
4Bq	260†	Tamarind fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Hood River
1Bg	100†	Tamarind fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Benton
1Ab	150†	Chili-coated lollipop	Chili, salt	Benton
1Ac	150†	Fruit-flavored candy coated plastic spoon with chili/fruit sauce	Tamarind, chili, salt	Benton
1Ba	90	Sweet/sour mango	Chili, salt	Benton

		powder		
1Bb	80	Mango flavored lollipop	Chili, salt	Benton
1Bc	120†	Fruit flavored lollipop	Chili, salt	Benton
1Bd	100†	Clear packet of tamarind pulp	Tamarind, chili, salt	Benton
1Be	110†	Tamarind fruit roll coated with chili/salt	Tamarind, chili, salt	Benton
1Bf	80	Mango flavored lollipop	Chili, salt	Benton
1Bgl	150†	Tamarind fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Benton
1Ca	100†	Lollipop with a fruit gummi	Chocolate, marshmallow	Benton
1Cb	110†	Hard candy lollipop	Chili, salt	Benton
1Cc	90	Sweet/sour powder	Chili, salt	Benton
1Ce	130†	Loose in bulk jar: appears coated with chili	Unknown	Benton
2Ab	80	Tamarind fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Marion
2Ac	80	Tamarind fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Marion
2Ad-c	300†	Tamarind fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Marion
2Ae-c	100†	Tamarind fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Marion
2Bb-c	140†	Tamarind fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Marion
2Be-c	130†	Tamarind fruit	Tamarind,	Marion

		roll on a stick coated with chili/salt	chili, salt	
2Bf-c	200†	Tamarind fruit roll on a stick coated with chili/salt	Tamarind, chili, salt	Marion

†Meets or exceeds FDA Guideline for candy 100 μg

Table 3.4 Chi-square 4 x 3 Analytic Lead Values by Main Ingredient

	Tamarind	**Chili**	**Salt**	**Total**
Below the RL (<80 or <90 μg/kg)	24	68	65	157
80-120 μg/kg	8	17	18	43
130-200 μg/kg	8	16	16	40
210-2200 μg/kg	3	14	11	28
Total	43	115	110	268

Table 3.5 Total Lead in Imported Mexican Candy by Weight

Sample Number	**Serving Size (g)**	**Lead/ Piece (μg)**	**Total Lead/ Two Pieces (μg)**	**Total Lead Four Pieces (μg)**
3Ab	44.79	9.85*	19.7*	39.4*
3Ac	25	13.5*	27*	52*
3Ae	28	5.6	11.2*	22.4*
3Af	15	2.85	5.7	11.4*
3Ag	20	3.8	7.6*	15.2*
3Ai	9	1.26	2.52	5.04
3Aj	19	2.09	4.18	8.36*
3Ak	28.35	62.37*	124.74*	249.48*
3Al	20	6.2*	12.4*	24.8*
3An	9	2.16	4.32	8.64*
3Ao	14	2.52	5.04	10.08*
3Ar	No serving			

	size or wt			
3Ba	45	10.8*	21.6*	43.2*
3Be	22.7	4.54	9.08*	18.16*
3Bi	5	4	8*	16*
3Bk	35	5.95	11.9*	23.8*
3Bl	15	2.7	5.4	10.8*
3Bm	48	3.84	7.68*	15.36*
3Bo	15	4.5	9*	18*
3Ca	45	6.3*	12.6*	25.2*
3Cg	15	3.45	6.9*	13.8*
3Ch	14	2.38	4.76	9.52*
3Ci	35	3.85	7.7*	15.4*
3Cp	24	5.04	10.08*	20.16*
3Da	45	13.5*	27*	52*
3Db	40	6.4*	12.8*	25.6*
3Dc	20	2	4	8*
3Di	15	2.7	5.4	10.8*
3Dj	5	0.55	1.1	2.2
3Dk	14	1.82	3.64	7.28*
3Dn	56.6	20.376*	40.752*	81.504*
3Dr	21	3.78	7.56*	15.12*
4Ac	No serving size or wt.			
4Ag	25	2.75	5.5	11*
4Al	23	4.14	8.28*	16.56*
4Ao	20	40*	80*	160*
4At	25	7.5*	15*	30*
4Bb	45	20.7*	41.4*	82.8*
4Bf	15	2.85	5.7	11.4*
4Bj	35	14*	28*	56*
4Bo	35	7.7*	15.4*	30.8*
4Bp	40	40*	80*	160*
4Bq	60	15.6*	31.2*	62.4*
1Bg	40	40*	80*	160*
1Ab	17	2.55	5.10	10.20*
1Ac	43	6.45*	12.90*	25.8*
1Ba	20	1.80	3.60	7.20*
1Bb	25	2.00	4.00	8.00*
1Bc	No wt	—	—	—
1Bd	No wt	—	—	—
1Be	45	4.95	9.90*	19.80*
1Bf	16	1.28	2.56	5.12

1Bg1	40	6.00*	12.00*	24.00*
1Ca	45	4.50	9.00*	18.00*
1Cb	25	2.75	5.50	11.00*
1Cc	5	0.45	0.90	1.80
1Ce	No wt	—	—	—
2Ab	40	3.2	6.4*	12.8*
2Ac	40	3.2	6.4*	12.8*
2Ad-c	40	12.00*	24.00*	48.00*
2Ae-c	40	4.00	8.00*	16.00*
2Bb-c	40	5.60	11.20*	22.40*
2Be-c	40	5.20	10.40*	20.80*
2Bf-c	40	8.00*	16.00*	32.00*

*Meets or exceeds FDA PTTIL 6 μg lead/d

Table 3.6 Lead in Mexican Candy, Wrapper, and Sticks of One Brand (n=18)

Sample Number	County	Lead in candy (µg/kg)	Serving Size (g)	Lead/ Piece (µg)	Lead in wrapper (µg/kg)	Lead in stick (µg/kg)
1Bg	Benton	100	40	4.0	360	9600
1Bg2	Benton	<80	40	—	90	13,000
2Aa	Marion	<80	40	—	4500	6800
2Ab	Marion	80	40	3.2	2600	5400
2Ac	Marion	80	40	3.2	950	5800
2Ad	Marion	300	40	12.0	3500	5700
2Ae	Marion	100	40	4.0	1400	7400
2Af	Marion	<80	40	—	1600	6300
2Ba	Marion	<80	40	—	750	150
2Bb	Marion	140	40	5.6	1600	880
2Bc	Marion	<80	40	—	1200	190
2Bd	Marion	<80	40	—	1000	130
2Be	Marion	130	40	5.2	1200	<90
2Bf	Marion	200	40	8.0	1600	120
3Cc	Mult	<80	40	—	5200	96,000
3Cd	Mult	<80	40	—	5900	38,000
4Ak	Hood River	<80	40	—	1800	63,000
4Bp	Hood River	1000	40	40	1900	<80
Min-Max lead (µg/kg)		<80-1000		3-40	90-5900	<80-96,000
Mean lead (µg/kg)		118		9.5	2064	14,359
Standard Deviation		236		12	1652	25,913

Figure 3.4 Scatterplot of Lead in Candy Vs. Lead in Sticks

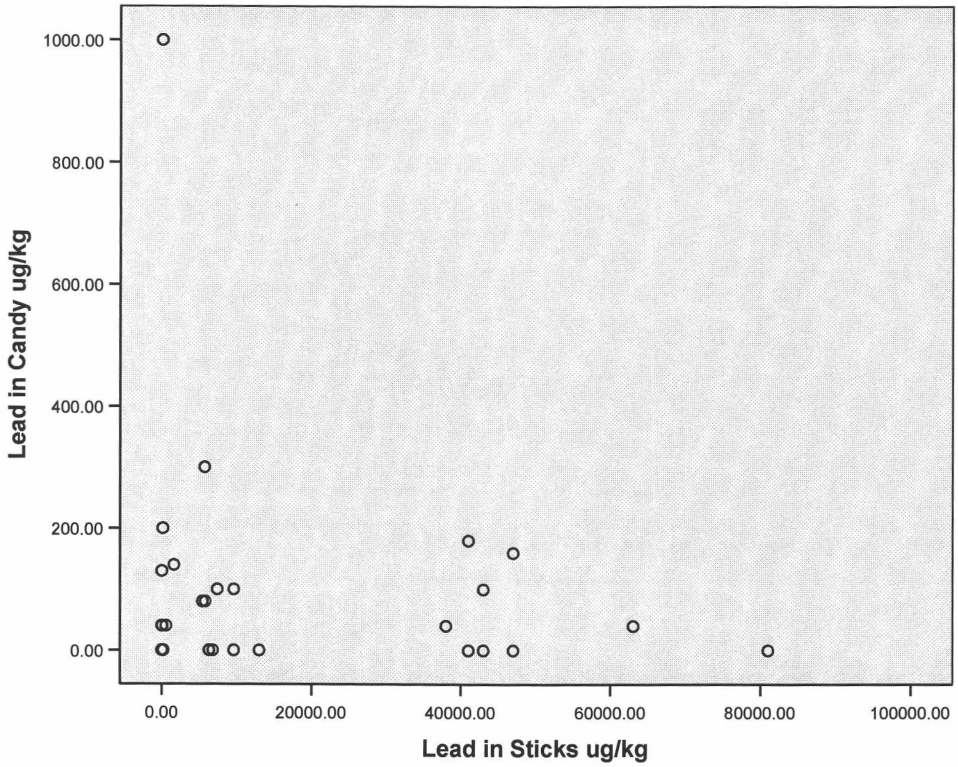

Figure 3.5 Scatterplot of Lead in Candy Vs. Lead in Wrappers

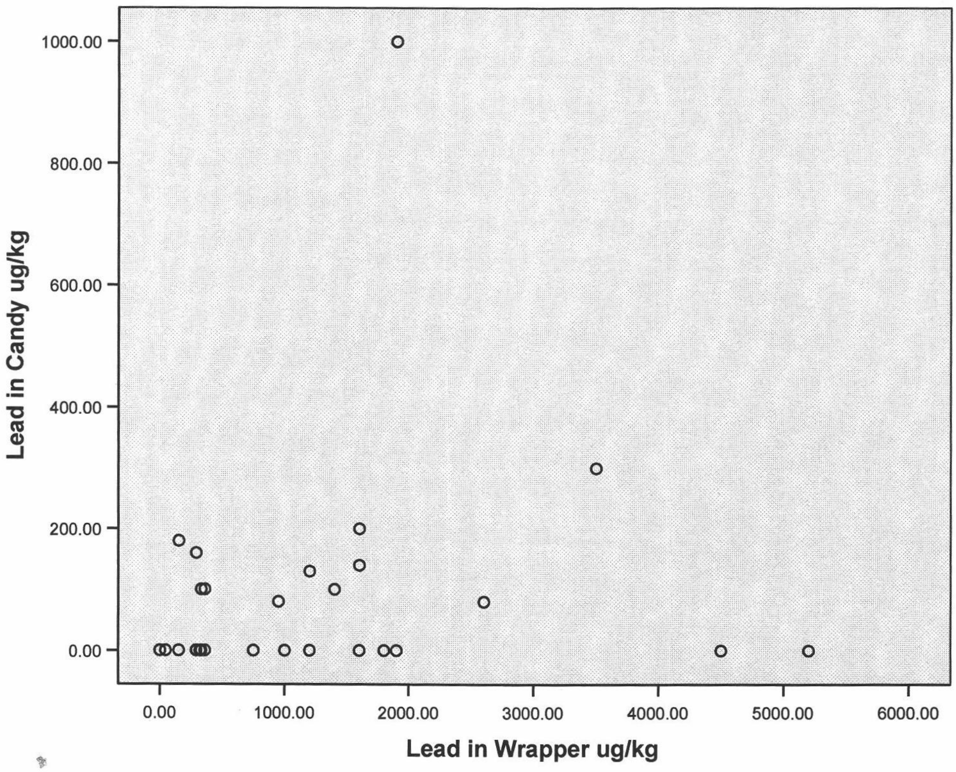

Table 3.7 Default Values of Media of the IEUBK Model

Age	Air (µg/d)	Diet (µg/d)	Water (µg/d)	Soil + Dust (µg/d)	Total (µg/d)	BLL (µg/dL)
0-11mo	0.021	2.553	0.359	4.061	7.004	3.8
12-23 mo	0.034	2.647	0.916	6.399	9.997	4.2
24-35 mo	0.062	3.002	0.962	6.462	10.488	3.9
36-47 mo	0.067	2.919	0.992	6.536	10.514	3.7
48-59 mo	0.067	2.863	1.048	4.930	8.908	3.1
60-71 mo	0.093	3.040	1.112	4.467	8.712	2.7
72-84 mo	0.093	3.366	1.135	4.231	8.825	2.5

Table 3.8 IEUBK Model Output

Age in months	BLL (µg/dL) with no alternate source of Lead	BLL (µg/dL) with **10** µg alternate Lead **(daily)**	Percent increase	BLL (µg/dL) with **40** µg alternate Lead **(daily)**	Percent increase	BLL (µg/dL) with **10** µg alternate Lead **(weekly)**	Percent increase	BLL (µg/dL) with **40** µg alternate Lead **(weekly)**	Percent increase
0-11	3.8	5.9	55%	**11.2**	195%	4.1	8%	5.0	32%
12-23	4.2	5.9	40%	**10.5**	150%	4.4	5%	5.2	24%
24-35	3.9	5.4	39%	9.5	144%	4.1	5%	4.8	23%
36-47	3.7	5.2	41%	9.1	146%	3.9	5%	4.5	22%
48-59	3.1	4.6	48%	8.5	174%	3.3	6%	4.0	29%
60-71	2.7	4.1	52%	7.9	193%	2.9	7%	3.5	30%
72-84	2.5	3.8	52%	7.1	184%	2.7	8%	3.3	32%

Chapter 4

General Conclusion

Lead has been used by human beings for thousands of years in cosmetics, paints, medicines and manufacturing processes. Lead is also found naturally in soil and can migrate into food, air, and water. The health problems associated with lead exposure have been anecdotally reported for thousands of years and well-known for the last one hundred years. Occupational lead exposure is still a significant source for adults in the U.S. In children, the sources of lead exposure in the last century have been from leaded paints, gasoline, soldering in food cans, and imported items such as medicines, cosmetics, and food.

At high doses, lead can cause death in adults and children. Children appear to be more sensitive than adults to lead exposure and can exhibit abdominal pain, joint pain, headaches, behavioral changes, convulsions, and loss of consciousness. BLLs have been declining over the last twenty years because some exposures have been reduced or eliminated (leaded gasoline, leaded paints, soldering in food cans). However, also in the last twenty years, a significant body of research has emerged that shows the devastating effects of low dose lead exposure on children's intelligence and behaviors.

Several studies have shown that there is no safe threshold for lead exposure in children. Cognitive deficits associated with lead exposure have been shown in toddlers, pre-schoolers, and school-age children. Delinquency and behavior problems have also been associated with lead exposure. Deficits in IQ points have repeatedly been associated with lead exposure. Some studies have even shown cognitive deficits that persisted into adulthood from childhood exposures to lead. Studies have also shown that the effects on intelligence and behavior may be exacerbated by poverty and poor nutrition.

There are emerging lead-contaminated products which continue to affect children's health. Many of these sources are from imported products such as Mexican candies. This source of lead exposure in children has been well-known to the U.S. Food and Drug Administration (FDA) for the last twelve years. Ink on wrappers and candy ingredients (chili, tamarind, salt) have been investigated as possible sources of lead. A number of import alerts and recalls have been issued by FDA, and in 2004 a general alert was issued advising the public not to allow children to eat any candies with chili and tamarind from Mexico. Moreover, FDA lowered the maximum allowable amount of lead in imported candies from 0.5 ppm to 0.1 ppm.

In 2004 in California, the *Orange County Register* (OCR) conducted an intensive investigation into the issue of lead-contaminated candies from Mexico, spurring the State of California to enact legislation to protect children from lead exposure from Mexican candies. Several grass-roots organizations emerged as result of OCR's investigation and as a result of their actions an agreement was reached with the State of California and the Mexican candy manufacturers in order to eliminate lead in imported candies.

In 2005 when this study was initiated, there had only been one published study on the topic of lead-contaminated candies imported from Mexico. In addition, several representatives from organizations in Oregon who work with lead issues in children expressed the need for research on this topic in order to better serve the families with whom they work. Therefore, a grant was submitted and subsequently approved to fund this study.

The results of this study suggest that lead-contaminated candies are readily available in the four counties selected for study. Almost half of the samples had lead above the Reporting Limit (RL) and almost 4/5's of these exceeded FDA's new guidance of 0.1 ppm lead. The results of this study did not show that any ingredient had more lead than any other. However, the amount of lead that could be ingested by a child when the weight of a particular candy and the number of pieces consumed were assessed was from 10 to 41 times FDA's Provisional Total Tolerable Intake for Lead (PTTIL) of 6 μg lead/day. It is important to remember that FDA's PTTIL is based on all sources of lead a child might encounter, not just from one source such as lead-contaminated candies.

One objective of this study was to try to determine the relationship between lead in the candies and lead in the stick or lead in the wrapper for one selected brand. No relationship was found between the lead in candies and lead wrappers. A negative correlation was found between lead in the candies and lead in the sticks. This test does not determine causality and it is still unknown from where the lead originates. However, high levels of lead were found in many of the wrappers and most of the sticks for this brand. This is highly concerning as it is unknown if the lead is bioavailable when children chew on the sticks (and possibly wrappers).

The U.S. Environmental Protection Agency's (EPA) Integrated Exposure/Uptake Biokinetic (IEUBK) model predicted geometric BLL increases in all age groups from daily and weekly consumption of two candies. Some BLL's were predicted to increase as much as 195%. In the two youngest age groups (0-11 mo.; 12-23 mo.) BLLs were calculated to exceed the U.S. Centers for Disease Control and Prevention's (CDC) elevated blood lead concentration for children and adolescents of 10 μg/dL with daily consumption of a candy with 40 μg lead.

The data from this study show that lead-contaminated candies are available in the four counties selected for study. This study also shows that the lead levels in some of the candies are high enough to potentially cause increases in very young children's BLLs from daily ingestion. In addition, the amount of lead found in the sticks of one brand selected for study is extremely concerning because of the lack of investigation on the bioavailability of lead in such sticks. For these reasons, and because of the catastrophic effects on children's health, behaviors, and intelligence from lead exposure, further academic research and governmental investigation is merited in order to provide the most protection possible to vulnerable young children.

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