

LEAD CONTAMINATION IN CANDIES IMPORTED FROM LATIN AMERICA

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ABSTRACT

Lead Contamination in Candies Imported from Latin America

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The problem of lead in candies imported from Latin America is an important health disparities issue as it particularly affects the health of children living in Latino Diasporas in the United States. Our research team at the University of Nevada Las Vegas was the first to employ the X-ray fluorescence (XRF) machine in the screening of candies for lead. The XRF is a novel instrument that can quickly, efficiently, and cost-effectively test for lead contamination. Once contaminated candies were identified, an exhaustive review of applicable laws and polices that can be utilized in the regulation of imported toxic candies was performed and, working in partnership with the Southern Nevada Health District, a Cease and Desist Order was issued based on our XRF findings. This paper traces the trajectory of the laboratory work performed and the legal research conducted that eventually lead to the issuance of the Cease and Desist Order. A thorough review of the laboratory-to-community translational research we achieved provides an important resource for both researchers and public health officials collaborating in the effort to remove contaminated candies from the shelves of stores and markets to ensure the health and safety of children.

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For me, this project is the perfect coupling of exercising my laboratory skills and utilizing the scientific method in performing research while simultaneously addressing important health disparities and social justice issues. Each of the aforementioned people saw the potential in me and encouraged me to pursue my passions. Being a part of this research project lead me down paths and sparked interests in me that had never existed before. Working as a team member, developing leadership skills, and learning how to interact with the media are but a few of the tools I have developed while performing my research. I thank everyone who has shared their wisdom with me. They helped me learn and grow on both academic and personal levels.

CHAPTER 1

INTRODUCTION

The problem of elevated blood lead levels (BLLs) is an important health disparities issue that particularly adversely affects the health of children living in Latino Diasporas in the United States (U.S.). Research suggests that children from low-income families and children who have migrated to the U.S. from developing countries are at a higher risk for lead exposure than their more affluent counterparts.¹ One troubling source of lead exposure is candy imported from Latin America. Many contaminated candies have ethnic origins and are marketed towards the Latino demographic, which makes children in the Latino community more likely to consume these types of candies than children from other populations. As the population of the Spanish-speaking community rapidly increases in the U.S., it is imperative that regulatory steps are taken to protect the health of Latino children. Though the U.S. Food and Drug Administration (FDA) has recently issued a warning about the dangers of consuming certain Mexican candies that have tested positive for lead, the scope of the problem has not been fully recognized and still there has been no official regulatory legislation enacted. The lack of specific regulations has caused a breach in public knowledge about the dangers of toxic candies and contributes to the degradation of the health of children.

Tamarind and chili flavoring gives many candies a uniquely spicy taste, but these types of candies have been identified as containing elevated levels of lead in the food

product or the packaging materials. Agricultural and packaging procedures may contribute to both deliberate and unintentional practices which cause the incorporation of lead into the food product. For example, in certain agricultural processes chilies are not cleaned before they are ground, which results in soil containing lead being mixed into the chili. In fact, "More than 90 percent of ground-chili samples bought in Mexico contained lead...Dirt, which contains lead, clings to many chilies."² Lead arsenate, a pesticide still used throughout Mexico, may also contaminate the candy products. Also, because middlemen and farmers are paid by the pound, they sometimes weigh down the bags of chiles with lead so profit margins can be increased. Chiles used in the manufacture of some candies are dried with leaded gasoline powered fans, another potential source of lead.³

Questionable agricultural practices are not the only way candies can become contaminated with lead. Some Mexican candy is packaged in clay pottery, which is often sealed with a lead-based glaze that can leach into the candy. Similarly, lead in wrappers is a concern since some wrappers are printed with leaded inks that have the capability to leach into the candy product. There is a disincentive for using lead-free inks in wrappers. Packaging costs would double for companies, thereby making the change from leaded to unleaded inks unprofitable for the manufacturers.⁴

The objective of this paper is to provide a comprehensive background on lead which will include the chemistry and toxicity of lead, as well as its natural and anthropogenic sources. There will also be an analysis of candies that contain lead and a detailed investigation into the adverse health effects of lead poisoning so the scope and

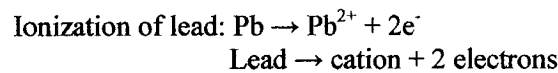
severity of lead exposure can be understood within a public health context. There will also be an evaluation of the complexities surrounding the regulation of lead in candy.

CHAPTER 2

REVIEW OF RELATED LITERATURE

Chemistry

Lead is a bluish white lustrous metallic material. Several physical and chemical properties intrinsic to metals set them apart from other elements. Metals are highly malleable, relatively soft, and have high electrical and thermal conductivity. Additionally, metals have a tendency to ionize in solution due to their weakly held valence electrons. When the metal ionizes, it gives up one or more electrons to form a positively charged ion.⁵



The degree to which the metal can ionize determines its other behaviors and, ultimately, its toxicity. As pH decreases, metals tend to become more mobile in the environment, resulting in a higher likelihood for exposure.⁵

The characteristics inherent to metals greatly influence their absorption, distribution, metabolism, and elimination in biologic systems. The three main routes of exposure are inhalation, oral, and dermal. The route of exposure may influence the distribution of the metal within the biologic system thus affecting its metabolism, potential toxic effects, and excretion.⁵ The bulk of this paper will concentrate on oral as the main route of exposure to lead since the research focuses on the consumption of candies.

Metals are elements and do not degrade in the environment. This is of concern to human health because their persistence results in a greater potential for exposure than other, less persistent, toxic chemicals. Metals may exist in the environment as elements or as complexes with other substances. Many metals have important biologic roles and are necessary for good health. However, lead is considered a nonessential/non-nutrient metal since it has no known beneficial role in biologic function.⁵

The use of lead in industry and construction is desirable because it is highly resistant to tarnishing upon exposure to air. Common industrial uses for lead are batteries, wire and cable, and alloys.

Table 1. Characteristics of Lead⁵

Name	Lead
Symbol	Pb
Atomic Number	82
Atomic Weight	207.2
Standard State	Solid at 298 K
Color	Bluish White
Classification	Metallic

Lead Toxicity

Lead is poisonous to humans upon exposure due to its toxicity towards multiple organ systems. The principle toxic effects of lead include damage of the hematopoietic, kidney, and neurological systems.⁵

Hematotoxicant

Lead poisoning has the ability to affect the normal functioning of red blood cells (RBCs) in the body. For example, it can interfere with heme synthesis in the liver

leading to anemias. This results in the premature destruction of RBCs, also known as *basophilic stippling* (appendix II). *Basophilic stippling* is characterized by purple granules that accumulate due to the inhibitory effects lead has on erythrocyte pyrimidine-5-nucleotidase, the enzyme that normally breaks down pyrimidine nucleotides. The blood-lead threshold affecting porphyrin biochemistry is approximately 25-30 µg/dL and the threshold for affecting hemoglobin is approximately fifty (50) µg/dL. Lead poisoning (defined as BLLs elevated equal or greater than ten (10) µg/dL) is treated by chelating therapy with drugs such as penicillamine, EDTA, Dimercapol, or BAL (British anti-lewisite).⁶

Nephrotoxicant

In humans, lead is characterized as a nephrotoxicant. Lead, along with cadmium and mercury, are classified as metal nephrotoxicant agents of principal concern. Lead primarily targets the proximal tubule of the nephron, causing the suppressed reabsorption of glucose, phosphate, and amino acids (appendix III). This can lead to glycosuria, aminoaciduria, and a hyperphosphaturia with hypophosphatemia. However, if the lead exposure is acute, these changes are reversible with chelating treatment. Chronic lead exposure may cause irreversible dysfunction and morphologic changes, resulting in eventual renal failure and death.⁷

Table 2. Industrial Operation with Exposure to Nephrotoxicants⁷

Industrial Operation	Nephrotoxicant
Amalgam Manufacturers	Mercury
Chemists	Chloroform
Chloralkali	Mercury
Dry Cleaning	Perchloroethylene
Manufacturing Batteries	Mercury, Lead, Cadmium
Manufacturing Cellulose Acetate	Dioxane
Metal Degreasing	Perchloroethylene
Paint Manufacturers	Lead, Cadmium
Plumbers	Lead

Neurotoxicant

Lead, as well as other metals such as thallium and triethyltin, can cause the demyelination of the sheath that surrounds the neurons of the central nervous system and some of the peripheral nervous system (appendix IV). Exposure often occurs in an industrial setting in which the metal can be easily inhaled. The metal can then directly attack the myelin sheath or disrupt the Schwann cells and oligodendrocytes. The damage resulting from such exposure can range from vision loss to impaired cognition.⁸ Lead is particularly harmful to the development of the nervous systems of fetuses and young children and extremely high BLLs (i.e., $\geq 70 \mu\text{g/dL}$) can cause severe neurological problems such as seizure, coma, and death. However, no threshold has been established regarding lead's negative effects on the learning and behavioral development of children.⁹

Table 3. Common Neurotoxic Metals⁸

Chemical	Symptom(s)	Site(s) of Action
Arsenic	Seizures, tremors	Peripheral motor nerves
Barium	Muscle spasms	Ion channels
Lead	Insomnia, tremors	Myelin, synapse, axon
Manganese	Insomnia, confusion	Synapse
Mercury (organic)	Ataxia, tremors, confusion	Peripheral motor neurons, axon
Thallium	Seizures, psychosis	Myelin, axon
Tin (organic)	Headache, psychosis	Myelin

Sources of Lead in the Environment

Natural Sources

Metals are naturally occurring elements in the earth's crust. Lead is found in soils, sediments, surface and groundwaters, and air. The inherent persistence of lead and other metals in the environment contributes to their role in various ecologic cycles. Less than one (1) ng/m³ of lead is found in the air, while 1-60 µg/L is found in drinking water. An additional 5-25 mg/kg is found in soil and only less than one (1) µg/L is found in rivers and lakes.¹⁰

Anthropogenic Sources

Humans play an important role in the transformation, mobilization, and accumulation of metals in the environment. Mining, dredging, construction, and manufacturing all remove metals from their natural locations and enhance their presence in natural biogeochemical cycles. For example, the addition of one form of lead, tetraethyl lead, to gasoline can increase the amount of lead to which people living in urban environments are exposed. Additionally, lead-based paints and lead pipes cause an unnatural increase in human lead exposure.¹¹ Though regulation has been passed to

discontinue the use of lead in gasoline, paint, and plumbing—efforts which have dramatically decreased human exposure—there has yet to be official regulatory action taken against lead found in other, less likely sources, such as in candies.

Though we know lead is found in certain candies imported from Latin America, the source of the lead and where the lead is concentrated in the product is still uncertain. My research explores various aspects of the manufacture and distribution of contaminated candies that may cause the incorporation of lead into the product and, using x-ray fluorescence (XRF) technology, determines where in the product the lead is found. Even though contaminated candies pose a risk to the health and development of children, conflicting forces at the international and domestic levels make regulatory action difficult. This study will research applicable laws and policies for regulation and recommends ways in which exposure to contaminated candies can be reduced.

Health Effects and Demographic Determinants of Lead Consumption

Lead is toxic to humans, especially for children under age six (6) and pregnant women. Lead poisoning affects children worldwide. In the U.S., lead poisoning is defined as BLLs equal or greater than 10 micrograms per deciliter ($\mu\text{g}/\text{dL}$).¹² The National Health and Nutrition Examination Surveys 1999-2000 survey estimated that close to 500,000 children aged 1-5 years had BLLs $\geq 10\mu\text{g}/\text{dL}$.¹³ Lead poisoning results primarily from exposure to lead-based paint or lead-contaminated dust or soil; however, it has been recently discovered that other sources of exposure include lead-contaminated candies imported from Latin America.¹² Lead is toxic to multiple organ systems, including the urinary, nervous, endocrine, and reproductive systems. Delayed mental and

physical development and learning problems can occur if an individual is subject to regular lead exposure.¹⁴ Lead is stored in different tissues in the body and specifically targets the central nervous system (CNS). The CNS is particularly susceptible to retaining lead for longer periods of time. In developing children the blood-brain barrier is still forming, which renders it more permeable. This allows lead to pass more readily into the brain.¹⁴

Between 1960 and 1990 the acceptable BLL in children was lowered from 60 $\mu\text{g}/\text{dL}$ to 25 $\mu\text{g}/\text{dL}$. In 1991, the standard was lowered to 15 $\mu\text{g}/\text{dL}$.¹⁵ Presently, lead poisoning is defined for children as an elevated BLL of 10 $\mu\text{g}/\text{dL}$ or higher.¹⁶ Unsafe lead levels are considered to be those that meet or exceed what regulators call the “level of concern.”

The U.S. FDA sets the level of concern for lead in food products at 0.5 parts per million (ppm), though in reality no level of lead in food is safe.³ For example,

At 3 ppm, a child would only need to eat 2 grams, less than half a teaspoon, of chili to exceed the daily maximum lead level considered safe. In some cases, that would be just one lollipop or one candy packaged in a clay pot, a common container for sticky Mexican candy.³

Research shows that Latino children and adolescents are at a disproportionately higher risk for lead exposure than their non-Latino counterparts. According to data collected from the Third National Health and Nutrition Examination Survey, “approximately 5% of Mexican-American children 1 to 5 years of age have blood-lead levels at or above [10 $\mu\text{g}/\text{dL}$] and an additional 23% have BLLs at 5 $\mu\text{g}/\text{dL}$.”¹ Although 5 $\mu\text{g}/\text{dL}$ does not currently qualify at the intervention level it is still a worrisome statistic, especially considering that chronic lead exposure, even at low levels, can manifest its deleterious effects on development in children.¹⁵ Additionally, “5% of Mexican-

Americans 6 to 19 years of age have BLLs of 10 µg/dL or higher.”¹ The U.S. Department of Health and Human Services (HHS) has developed an ambitious goal of eliminating elevated BLLs in children by the year 2010. These staggering figures demonstrate the gravity of the problem in the Latino community.¹⁵ In order to meet the goal set by the HHS, swift and decisive action is required immediately.

Lead poisoning is the most preventable form of poisoning in children. The fact that the reduction of lead in the environment is feasible makes it more of a tragedy that children are still experiencing lead’s negative health effects. Eliminating children’s exposure to lead is essential in securing the unimpaired integrity of their health and development.

Regulation

An exploration into how food quality is upheld in the United States and the complexities of regulating the importation and distribution of lead contaminated candies is important. International, domestic, and local food regulations need to be investigated through an analysis of globalization and the North American Free Trade Agreement (NAFTA) and key legislative pieces of the Food Acts that have worked to set precedents in food quality. Notable applications from the 2005 Food Code and the Consumer Product Safety Act (CPSA) also need to be reviewed, as well as the Nevada Revised Statutes (NRS). Finally, a bridge should be drawn between the health problems that are associated with lead in candy and the regulatory measures that need to be implemented to prevent lead poisonings.

CHAPTER 3

QUESTIONS, OBJECTIVES, AND HYPOTHESES

Questions

- Are there candies that test positive for lead using the XRF that are not identified on the “California Toxic Treat List”?
- Where is lead found in the candy?
- Do countries other than Mexico manufacture leaded candies?
- Is type of candy (chili/tamarind, hard, chewy, lollipop) related to positive or negative lead content?
- How can contaminated candies be regulated?

Objectives

- Identify candies that contain lead.
- Identify which part of the candy and its components contains lead.
- Identify the countries in which contaminated candies are manufactured.
- Provide suggestions for regulation.

Hypotheses

“California Toxic Treat List”

The “California Toxic Treat List”, developed by researchers in Southern California, has become the linchpin in contaminated candy identification.

- There will be candies that contain lead that are not identified on the “California Toxic Treat List.”

Using the XRF, I will determine whether or not the candy has a positive test result for lead. Through a visual examination of raw data, I will compare my results to the “California Toxic Treat List” to check if it is a brand of candy that has been identified as containing lead in previous research. I will be comparing seven different brands of candy: Banderilla Tama Roca, Margarita Dulce de Tamarind Clay Pot, Tamarind Plastic Pot, Montes Super Natilla, Peccin Sour Chews, Strawberry Filled, and Bob Esponja. Table 4 identifies the seven different brands of candies, various components of the candies, sample sizes obtained, and whether or not they are included in the list. Though the “Toxic Treat List” is a comprehensive gathering of contaminated candies, it is important to ascertain how complete it is so modifications can be made to it so the public can be more aware of the range of possibly dangerous candies that exist.

Table 4. Name, Packaging, Sample Size, Toxic Treat List

Name	Packaging	N=	Toxic Treat List
Banderilla Tama Roca	Candy	15	Yes
	Wrapper	15	
	Straw	15	
Margarita Dulce de Tamarind Clay Pot	Candy	6	Yes
	Pot	6	
	Spoon	7	
Tamarind Plastic Pot	Candy	10	No
	Pot	10	
	Spoon	10	
Montes Super Natilla	Candy	26	No
	Wrapper	35	
Peccin Sour Chews	Candy	24	No
	Wrapper	21	
Strawberry Filled	Candy	25	No
	Wrapper	25	
Bob Esponja	Candy	25	No
	Wrapper	25	

Candy Accessories

Previous research has identified which candies have tested positive for lead, but the research has not identified where in the candy the lead is concentrated.

- Lead will be found more often in accessories associated with the candy (spoons, straws, pots, wrappers) than in the food itself.

The Chi-squared for multiple proportions statistical method will be utilized to compare the brand of candy with its component unless the expected values calculate to be less than five (5) in which case a Likelihood Ratio test will be performed (Zar, 1999). The seven brands of candies to be analyzed are: Banderilla Tama Roca, Margarita Dulce de Tamarind Clay Pot, Tamarind Plastic Pot, Montes Super Natilla, Peccin Sour Chews, Strawberry Filled, and Bob Esponja. The five different components are: candy, straw,

pot, spoon, and wrapper. Because the amounts and types of components associated with each brand of candy vary, it is best to combine data to maximize counts in contingency tables. Therefore, two separate tables will be constructed. One table will perform a comparison between the food itself and the accessories for Banderilla Tama Roca, Margarita Dulce de Tamarind Clay Pot, and Tamarind Plastic Pot since these three candies have multiple components (straw, pot, spoon) associated with them. A second comparison will be drawn between the food itself and the wrappers for Banderilla Tama Roca, Montes Super Natilla, Peccin Sour Chews, Strawberry Filled, and Bob Esponja. By performing these statistical analyses, I will be able to determine in which part of the candy, wrapper, or accessory the lead is more often found. This information is important in determining whether the contaminated candy should be regulated as a food product or as a contact surface.

Country of Manufacture

Though Mexico does manufacture candies that have tested positive for lead, there is the possibility that other countries throughout Latin America produce contaminated candies.

- Candies manufactured in countries other than Mexico will contain lead.

A multiple contingency table will be constructed to compare the country in which the candy is manufactured to positive or negative lead results (Zar, 1999). The three Latin American countries that will be compared are Mexico, Brazil, and Argentina (Table 5).

By performing this analysis, I will be able to determine whether the issue of contaminated candies is unique to Mexico, or if it is more geographically dispersed.

Table 5. Name, Type, Description, and Manufacturer Location

Name	Type	Description	Manufacturer Location
Banderilla Tama Roca	Tamarind/Chili	Candy with Straw	Mexico
Margarita Dulce de Tamarind Clay Pot	Tamarind/Chili	Candy in Clay Pot with Spoon	Mexico
Tamarind Plastic Pot	Tamarind/Chili	Candy in Plastic Pot with Spoon	Mexico
Montes Super Natilla	Chewy Candy	Chews	Brazil
Peccin Sour Chews	Chewy Candy	Sour Chews	Brazil
Strawberry Filled	Hard Candy	Hard Candy with Filing	Argentina
Bob Esponja	Lollipop	Lollipop	Mexico

Chili/Tamarind versus Other Types of Candy

Many candies that have been identified as containing lead are spiced with chili and/or tamarind flavoring.

- There will be mostly positive lead content results for chili/tamarind candy and mostly negative results for all other types.

A contingency table for type of candy will be constructed to compare positive or negative lead results to type of candy (Zar, 1999). The four different types of candies that will be compared are: tamarind/chili, chewy, hard, lollipop (Table 5). The four classifications are based on the physical properties of the candies. By performing this analysis, I will be able to better predict if it is possible to determine the probability of the candy containing lead based on its physical composition.

Candy Regulation

Once contaminated candies are identified, it is important to know the applicable laws and policies that are in place and how to utilize them in order to regulate toxic candies and protect the health of the community.

- There are laws and policies in place under which contaminated candies can be regulated.

I will perform an exhaustive review of applicable laws and policies at the international, federal, and local levels and perform an in-depth case study investigation into the Southern Nevada Health District Cease and Desist Order issued on contaminated candies in the Las Vegas Valley.

CHAPTER 4

CANDIES SELECTED FOR ANALYSIS AND SCREENING METHODOLOGY

There are candies that do contain lead that have not been identified in previous research. With minimal to no enforceable regulation in place and without any accountability for manufacturers and distributors of contaminated candies, the importation and distribution of leaded candies continues unabated. My research will identify previously unrecognized contaminated candies and develops a platform upon which federal, state, and local agencies can move towards regulation of hazardous candies and protect the health of children.

Criteria to determine which candies will be selected for analysis is based on type of candy (tamarind/chili, chewy, hard, lollipop) as well as manufacturer location (Mexico, Brazil, Argentina). Only candies manufactured in Latin America are selected. Additionally, candies packaged with spoons, straws, wrappers, or within clay or plastic pots are selected so the lead content of the packaging materials, in addition to the food product, can be analyzed.

Candies purchased in local stores and ethnic markets located in Las Vegas, Nevada and Los Angeles, California will be used in the analysis. Criterion for candy selection is that it is manufactured in Latin America. Additionally, a cross-section of types of candies is selected to determine if the lead is specific to tamarind and chili spiced

candies or to other types of candies such as chewy candies, hard candies, and lollipops (Table 5).

Currently, the most cost effective EPA approved method for screening lead in materials is Graphite Furnace Atomic Absorption Spectrometry (GFAA). GFAA is still a timely and costly process, though. For example, if candies were to be screened using GFAA each component (candy, spoon, straw, pot, wrapper) would cost approximately twenty-five dollars. The XRF will be used to screen candies, wrappers, straws, spoons, pottery, and any other component associated with the food product packaging. The EPA approved standards for screening lead in paint, soils, and dust wipes will be the basis upon which the XRF protocol is developed. The XRF equipment is an economically advantageous alternative for screening candies because all components of the candy and its packaging can be screened in a timely and efficient manner thus expediting the screening process and allowing more candies to be evaluated in a shorter amount of time and at a cheaper cost. By using the protocol that has been developed for screening candies using the XRF, this research will identify candies that contain lead and will provide government officials with laws and policies that can be used in their regulation. The motive driving the research is to protect the health of a larger population of children.

CHAPTER 5

RESULTS AND DISCUSSION

Several different analytical methods were employed to provide answers to the hypotheses. Through visual examination of raw data, I determined certain types of candies that contain lead that have not been identified on the “California Toxic Treat List”. In my statistical analyses I constructed multiple contingency tables and have used the Likelihood Ratio test where expected values are less than five (5) and the Chi-squared test where they are not. All analyses follow Zar (1999).

The Likelihood Ratio test was used to compare the food itself to the accessories and wrappers associated with the various brands of candies selected (Appendix VIII-A). By performing these analyses it was determined if the lead is more often found in the food itself, the accessories associated with the candies, or in the wrappers. This is important for regulatory measures to determine whether the candy should be regulated as a food product or as a contact surface.

A multiple contingency table was constructed and a Likelihood Ratio test was performed to compare the country in which the candy was manufactured to positive or negative lead results (Appendix VIII-B). This allowed an examination of whether the issue of contaminated candies is unique to Mexico, or if it is more ubiquitous.

A contingency table for type of candy was constructed and a Chi-squared test was performed to compare positive or negative lead results to type of candy (Appendix VIII-

C). By performing this analysis, the probability of a certain type of candy containing lead based on its physical composition could be ascertained.

Lastly, an exhaustive investigation into applicable laws and policies for candy regulation, which will include a case study investigation into the Southern Nevada Health District cease and desist order issued on certain types of candies, will be discussed.

“California Toxic Treat List”

Seven different brands of candies were tested to determine whether or not they contain lead and if they appear on the “California Toxic Treat List.” Though the candies were broken down into their individual components (candy, wrapper, straw, pot, spoon) a positive lead result in any of the components signifies contamination. Candies chosen that do appear on the list are Banderilla Tama Roca and Margarita Dulce de Tamarind Clay Pot. Those candies which do not appear on the list are Tamarind Plastic Pot, Montes Super Natilla, Peccin Sour Chews, Strawberry Filled, and Bob Esponja. The three components associated with Banderilla Tama Roca are candy, wrapper, and straw. The three components associated with Margarita Dulce de Tamarind Clay Pot and Tamarind Plastic Pot are candy, pot, and spoon. Montes Super Natilla, Peccin Sour Chews, Strawberry Filled, and Bob Esponja each have two components: candy and wrapper.

Two candy brands, Margarita Dulce de Tamarind Clay Pot and Peccin Sour Chews, tested positive for lead in the food itself. All seven brands tested positive for lead in the wrappers. Banderilla Tama Roca, the only candy tested associated with a straw,

tested positive for lead in the straw. Margarita Dulce de Tamarind Clay Pot and Tamarind Plastic Pot tested positive in both the pot and the spoon.

Table 6. Name, Packaging, Sample Size, +/- Lead Result, Toxic Treat List

Name	Packaging	N=	+/- Lead Result	Toxic Treat List
Banderilla Tama Roca	Candy	15	-	Yes
	Wrapper	15	+	
	Straw	15	+	
Margarita Dulce de Tamarind Clay Pot	Candy	6	+	Yes
	Pot	6	+	
	Spoon	7	+	
Tamarind Plastic Pot	Candy	10	-	No
	Pot	10	+	
	Spoon	10	+	
Montes Super Natilla	Candy	26	-	No
	Wrapper	35	+	
Peccin Sour Chews	Candy	24	+	No
	Wrapper	21	+	
Strawberry Filled	Candy	25	-	No
	Wrapper	25	+	
Bob Esponja	Candy	25	-	No
	Wrapper	25	+	

These results are important because they give insight into how candies should be regulated. If candies are only regulated if the lead is found in the food product itself, only two brands, Margarita Dulce de Tamarind Clay Pot and Peccin Sour Chews, qualify for regulation. However, if food contact surfaces are included in regulation, all brands tested would qualify since all brands, in at least one associated component, tested positive for lead. The “Toxic Treat List” does not designate in which component of the candy the lead was found. The research did identify brands of candy that contain lead that are not

identified on the “Toxic Treat List” and in which component of the candy the lead is concentrated.

Candy Accessories

Two contingency tables were constructed to compare the candy itself to either its components or its wrapper. It was found that for all three brands compared (Banderilla Tama Roca, Margarita Dulce de Tamarind Clay Pot, and Tamarind Plastic Pot) the component (straw, pot, spoon) tested positive for lead more often than the food itself and was independent of brand ($G=2.29$, $p=0.318$). This is because nearly all candies tested had identifiable amounts of lead in the accessories regardless of brand. When comparing the candy itself to the wrappers of Banderilla Tama Roca, Montes Super Natilla, Peccin Sour Chews, Strawberry Filled, and Bob Esponja it was found that wrappers tested positive for lead more often than the food itself and was independent of brand ($G=6.11$, $p=0.191$). Based on these results it can be concluded lead will be found more often in the accessories associated with the candy than in the food product itself regardless of brand. This is important for determining how candies should be regulated since there are different standards for regulating lead in food versus lead in contact surfaces.

Country of Manufacture

Based on a visual examination of raw data, it was determined that all countries included in this study (Mexico, Brazil, Argentina) manufacture candies that tested positive for lead in the wrappers and/or components. A contingency table was constructed to determine if lead found in the food itself is associated with country of

manufacture. It was determined that for all three countries detectable levels of lead in the food itself was independent of country of manufacture ($G=3.14$, $p=0.208$). This shows that the manufacture of contaminated candies is not limited to Mexico and that it is a more geographically dispersed problem.

Chili/Tamarind versus Other Types of Candy

A contingency table was constructed to compare chili/tamarind candy to all other types. The result was found to be significant ($\chi^2=22.042$, $p\leq 0.001$). There were more positive and more negative test results for lead than expected. A second contingency table was constructed to compare the four different types of candy (chili/tamarind, chewy, hard, lollipop) to each other. It was found that there is also a significant difference between positive and negative lead content in the types of candies analyzed ($\chi^2=6.931$, $p=0.034$). However, hard candies did not follow the distribution of the other types of candies. Hard candies contained fewer negative and higher positive counts than expected. As hypothesized, chili/tamarind type candies contained more lead than expected by chance. However, when we break down non-chili/tamarind into types of candy we are able to get a better picture of the overall trend. Hard candies have less lead than expected (overall $\chi^2=22.042$, $p\leq 0.001$; hard candy $\chi^2=6.931$, Bonferroni adjusted $p=0.034$).

Armed with the lead results from the XRF machine, it was logical that the next step that needed to be taken to protect the health of the public was to remove contaminated candies from the shelves of markets and stores. As a scientist it is important to not work in a vacuum, but to rather share findings and enact change. An

exhaustive review of applicable laws and policies that could be used in the regulation of contaminated candies was soon conducted. However, being able to effectively regulate lead-contaminated candy is a difficult feat. International, domestic, state, and local policies are often contradictory and in conflict with each other and food quality standards and guidelines are still under debate.

The subsequent sections of the paper review various laws and policies that have set precedents in food regulation and that can be applied to lead-contaminated candy. After the review of these laws and policies, there is a discussion on how we were able to successfully obtain a Cease and Desist Order in the Las Vegas Valley to ban contaminated candies. We are the first county in the country that has actually effectively followed the precautionary principle and has set regulations on lead-contaminated candies in order to protect the health of children and uphold public welfare.

Candy Regulation

Globalization and the North American Free Trade Agreement

Consumers in the U.S. have been buying candies manufactured in Latin America for years, a fact of globalization and the changing marketplace. This trend began “in 1969 [when] Hershey opened one of the first U.S.-owned candy factories in Mexico. Since then, nearly all the major companies—Tootsie Roll, Nestle, PepsiCo—have opened plants there [south of the border] mainly to take advantage of cheaper sugar and labor.”⁴ Part of the reason why regulation has been such a difficult feat for state and federal lawmakers in the U.S. is because the problem originates in Mexico where U.S. laws have no power. Additionally, Mexico does not impose any regulatory guidelines for lead in

candies. Owing to difficulties associated with inspecting candies at the U.S.-Mexico border, the FDA only inspects about two percent of merchandise that is brought into this country.¹⁶

Another factor that complicates regulation is that import and export versions of the same candies are made: one produced and packaged to be exported to the U.S. and one, with inferior quality standards, to be distributed throughout Mexico.¹⁶ Often, it is difficult to distinguish between the two versions. Many distributors in the U.S. travel to Mexico to buy candy because it is cheaper there, which can result in the Mexican version of the candy being brought into the U.S. for distribution.¹⁶ This practice can continue because “unless a candy is the subject of an FDA alert, importers can legally bring it in.”⁴ Though the FDA has known about different versions of the same candy, it has yet to take any action or implement any restrictions on this practice.

Without clear regulations, companies do not feel a sense of urgency to make safe candy. In many cases, these companies are unaware of the problem altogether. Health advocate Eileen Quinn, deputy director for the Alliance for Healthy Humans, a lead-poisoning prevention group in Washington, D.C., claims to have seen this problem before regarding the actions of lead-paint manufacturers who “knew their product had lead in it and chose to market it anyway... acting with deliberateness to put profits before public health.”⁴ Even though there is an active base of officials working to track lead in the air, water, paint, and food, standards for how much lead is harmful are still under debate. There is a trend toward reducing the safe level standards, thereby affording a greater level of protection against lead poisoning.

NAFTA was designed to create a more liberal economic market environment between the U.S., Canada, and Mexico. The foundation of the Agreement is an integration of the three countries' markets through the dismantling of trade barriers.¹⁷ It is unquestionable that the growing Latino population in the U.S. will coincide with an increase in the importation of ethnic candies to meet consumer demand. The demand is already being easily met since the NAFTA policy contributes to a less restricted flow of products across the border.¹⁸

There are several significant sections outlined in NAFTA, Part Two: Trade in Goods, Chapter Seven that directly relate to the regulation of lead-contaminated candies. Chapter Seven is entitled "Agriculture and Sanitary and Phytosanitary Measures" and discusses the maintenance of sanitary standards in food. Chapter 7, Section B-Sanitary and Phytosanitary Measures, Articles 712, 713, and 714 contain sections which thwart candy regulation.

NAFTA Article 712

Article 712: "Basic Rights and Obligations," paragraph 2 involves the concept of the *Right to Establish Level of Protection*. The paragraph discusses the right of each Party to protect the health of human, animal or plant life by establishing appropriate levels of protection.¹⁹ Currently, the health of children is not being protected and their exposure to candies containing lead continues unabated.

Also under Article 712 is paragraph 5, entitled *Unnecessary Obstacles*. This segment of the article requires that limitations be based on *Scientific Principles*, as discussed in paragraph 3, including risk assessments, and must allow economic and technical feasibility to be taken into consideration by manufacturers when trying to

achieve the “appropriate level of protection.”^{20, 21} The caveats of “feasibility” and “extent necessary to achieve its level of protection” serve as loopholes under which manufacturers do not have to uphold sanitary standards. Regulation is problematic because there is still debate surrounding the necessary level of protection for children with regard to lead exposure. Should the action level for blood lead be set at 10 µg/dL, the standard for lead poisoning or should the action level be set at 0.5 ppm, the food level of concern for regulators? Should the action level be zero, since realistically there is no safe level of lead in food? These are crucial questions that need answers so children’s health can be protected. Furthermore, what about food contact surfaces that contain lead, such as spoons, straws, containers, and wrappers, all of which can pose a danger to children’s health?

The third important point covered under Article 712 that warrants consideration is *Disguised Restrictions*. Paragraph 6 states, “No Party may adopt, maintain or apply any sanitary or phytosanitary measure with a view to, or with the effect of, creating a disguised restriction on trade between the Parties.”²² The terminology in this paragraph must be clarified with respect to its application to candies. Would the regulation of candies constitute a disguised restriction? Unless the protection of human health supersedes this restriction, it would be very difficult—if not impossible—to impose restrictions on the importation of these candies.

NAFTA Article 713

Article 713: “International Standards and Standardizing Organizations” also generates contentious topics with regard to candy regulation. Paragraph 1 of the article states that each Party must abide by “...relevant international standards, guidelines or

recommendations...” to make the sanitation of their product “equivalent... to those of the other Parties”.²³ This is a difficult standard to achieve since guidelines for food quality in the U.S. are still under consideration and, once decided, would be difficult to extrapolate to international standards. However, it would be prudent, as Article 713, paragraph 5 suggests, to be aware of and “participate in relevant international and North American standardizing organizations...”²³ This would provide access to the most recent lead-related standards being generated both in the Americas and abroad and the science on which they are based.

NAFTA Article 714

Article 714: “Equivalence” has some of the most interesting information regarding sanitation and trade. In paragraph 2, the article outlines the rights of importing Parties: “each importing party... may, where it has scientific basis, determine that the exporting Party’s measure does not achieve the importing Party’s appropriate level of protection.”²⁴ The scientific community in the U.S. has performed extensive research into the negative health effects of lead in children and has shown through procedures such as graphite furnace atomic absorption spectrometry and X-ray fluorescence that some candies imported from Latin America are sources of lead. When government officials have this knowledge, and yet continue to enforce stagnant, inapplicable regulations, they compromise the health of children. There is also the potential that health is being undermined in pursuit of achieving an international liberal market economy in which trade barriers are systematically dismantled.

NAFTA Article 715

Article 715 “Risk Assessment and Appropriate Level of Protection,” paragraph 3(a) states, “Each Party, in establishing its appropriate level of protection, should take into account the objective of minimizing negative trade effects...”²⁵ Completely ceasing the importation of certain candies could be considered a barrier to free trade and would thus potentially be deemed a violation of NAFTA.

Operating under the coercive threat of federal funding withdrawal, state and local governments can be forced to weaken their laws in order to abide by terms set by NAFTA and the General Agreement on Tariffs and Trade (GATT). State and local laws and regulations must be at least as stringent as the related federal codes. State and local rules can be, and often are, more specific than the federal regulations from which they are generated. With a better understanding of regional issues, state and local agencies frequently promulgate regulations which are directly relevant to the area. These regulations usually protect food and ban toxic substances more rigorously than international agreements such as NAFTA and similar U.S.-specific federal legislation. This can negatively affect food quality since these stronger regulations may be subject to challenge by the federal government. As a result, any domestic benchmarks for safety that provide greater levels of protection than industry standards may be considered trade barriers under NAFTA and force the lowering of standards.²⁶ It is argued that NAFTA requirements can put people at significant risk by refuting modern, protective health and consumer safety laws.

Federal Acts, Codes, and Regulations

An analysis of precedents set in food quality and other related regulations is beneficial for understanding the current regulatory state of lead-contaminated candies. The following sections of the paper will chronologically outline legislative efforts in food quality and the management of lead which affects human health and the environment, starting with the Federal Food and Drugs Act of 1906 (F&DA); moving on to the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA, FD&C Act, or FDCA), with significant amendments 1958 to present; then the Lead-Based Paint and Poisoning Prevention Act of 1971 (LBPPPA); and concluding with the Nutrition Labeling and Education Act of 1990 (NLEA).

In order to locate needed information when researching laws and regulations, one must understand the hierarchy of documentation provided by the federal, state, and local governments. Federal laws are conceived of and processed through the Legislative Branch of the U.S. government. A bill is evaluated, and may become a law.²⁷ These laws can be given titles such as “The Food and Drugs Act of 1906” and short titles such as “The Wiley Act” to identify them and their areas of concern.²⁸ Once laws are passed through Congress and are not vetoed by the Executive Branch of government, they may undergo scrutiny in the Judicial Branch. If the law passes a challenge determining that it is, indeed, Constitutional, then the law is codified and distributed for use. The set of documents which contain these codified Acts is called the “United States Codes” or “USC” for short. Further, agencies within the Executive Branch are assigned the responsibilities of enacting these codes in the areas of interest and manner for which they were intended. Some of these documents containing the day-to-day rules of operation are

called the Code of Federal Regulations (CFR). For instance, the FDA HHS; as well as the Drug Enforcement Administration (DEA), Department of Justice (DOJ) and the Office of National Drug Control Policy are responsible for implementing 21 CFR, Parts 1-1499, which are the regulatory documents generated to apply the Federal Food, Drug, and Cosmetic Act of 1938. The numbering system identifying each group of documents is not always the same, and one must conduct thorough and accurate research to ensure that he has located all versions of the rules that apply to the particular topic of interest.

The Federal Food and Drugs Act of 1906

The Federal Food and Drugs Act of 1906, also referred to with many synonyms such as the “Pure Food and Drug(s) Act(s)”, the “Wiley Act”, or simply the “Food and Drug(s) Act(s),” applied strict penalties for certain acts of adulteration and misbranding. In order to control adulteration, for example, the meat inspection regulations required that animals used to produce meat were generally disease-free and slaughtered in a relatively contamination-free environment. In the labeling of food products, ingredients such as morphine, alcohol, opium, and cannabis required to be listed if they were present in the food item.²⁹ The impetus of the F&DA was to protect public welfare by imposing manufacturer accountability for adulterated food products. However, candies were and still are adulterated with lead for various reasons as discussed previously, but have not been historically or currently regulated even though they have always posed a danger to the health of the public.

Federal Food, Drug, and Cosmetic Act of 1938

The F&DA was repealed and replaced by the Federal Food, Drug, and Cosmetic Act, enacted in 1938.³⁰ This section will review the FDCA specifically with significant

amendments 1958 to present. The FDCA itself, which was instituted to regulate the quality of consumer products, includes FD&C Act Numbers 1 through 909. The FDCA is codified in USC Title 21, “Food and Drugs”, Chapter 9, Sections 301 through 399. The chapters in both documents roughly mirror each other.³¹ In addition, 21 CFR Chapter I, Subchapter B, Parts 100 through 189, contains the day-to-day information for implementing the FDCA.³² Three important components to the FDCA which can be applied directly to the regulation of toxic candies are: the definition of adulteration, the composition of packaging, and the addition of substances for the purpose of increasing profit. In FDCA Section 402 (21 USC 342), adulteration is defined as a product that “...bears or contains any poisonous or deleterious substance which may render it injurious to health...”³³ Candies contaminated with lead can cause elevated BLLs which affect important organ systems and can lead to cognitive and developmental delays in young children.

FDCA Section 402 also discusses the issue of packaging and establishes grounds for regulation “if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render contents injurious to health.”³³ The packaging of and accessories associated with contaminated candies, such as wrappers, pots, straws, and spoons, contain lead which, under appropriate conditions, can leach into the candy itself (unpublished data).

Lastly, FDCA Section 402 states, “if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is,” then regulatory measures can be taken.³⁴ Farmers and middlemen intentionally weigh down bags of chiles with

lead as to increase their bulk weight thus increasing profit margin.² Lead contamination in any part of the candy or its packaging reduces its quality and can be regulated under this act. However, direct evidence of this practice would be difficult to provide.

The FDA is reluctant to take action against lead in wrappers because it claims wrappers are not ingested and therefore fall under the jurisdiction of Consumer Products Safety Commission.⁸ However, lead in wrappers can leach into the candy and pose potential health problems. In addition, children in the age group of greatest concern typically place packaging materials in their mouths in the process of consuming the candy. The FDA acknowledges lead in wrappers does fall under the FDCA and can be regulated if lead from the ink “can be reasonably expected to contaminate the food, either while it is held in the package or during the act of eating.”³³ However, no standard concerning acceptable levels of lead has been proposed nor provided.

Lead-Based Paint Poisoning Prevention Act of 1971

The Lead-Based Paint Poisoning Prevention Act, codified in USC Title 42 “The Public Health and Welfare”, Chapter 63 greatly helped in the reduction of lead exposure. The LBPPPA includes a provision which prohibits the application of lead-based paint to any drinking or eating utensil.³⁴ The intent of this provision is to prevent unintentional ingestion of lead through the use of the utensil or dishware. Lead has been found in spoons and straws associated with toxic candies (unpublished data). Lead may be added to spoons or straws to make them more pliable thus creating a potential route of exposure that could be regulated under this act. Additionally, high concentrations of lead have been found in the glazing used in pottery in which certain candies are packaged, which

constitutes a food contact surface. Some of these glazed pots contain excessively high levels of lead and are regulated at the border.

Nutrition Labeling and Education Act of 1990

The Nutrition Labeling and Education Act was implemented to make the consumer more aware of the contents of the food product.³⁵ The NLEA requires the labeling of a food product to include: the serving size, or other common household unit of measure customarily used; the number of servings or units per container; the number of calories per serving and derived from total fat and saturated fat; the amount of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, total protein, dietary fiber per serving or other unit; and vitamins, minerals, or any other nutrients that are in the food product and are deemed to be important for consumers to know about to maintain a healthy diet.^{33,36} The NLEA allows the consumer to make better-informed decisions regarding food consumption and health and establishes accountability for the manufacturers to disclose product contents. Many consumers of lead-contaminated candies are unaware they could possibly be ingesting a poisonous metal. Consumers are not given the right to make informed decisions about the product and their health may be compromised.

2005 Food Code

The *Food Code* is a regulatory model set by the U.S. FDA to assist food control at all levels of the government. The model is used by local, state, tribal, and federal regulators to update their own food safety rules and comply with national food safety standards.³⁷ Between 1993 and 2001, the *Food Code* was issued every two years. The U.S. FDA decided to have a four-year interval between complete Food Code revisions.

The *2005 Food Code* is the first complete edition to be published since 2001. During the 4-year interim period, a *Food Code* Supplement that updates, modifies, or clarifies certain provisions was made available.³⁸ Chapter four of the *2005 Food Code*, entitled “Equipment, Utensils, and Linens,” provides useful food safety standard information regarding food-contact surfaces. “MATERIALS FOR CONSTRUCTION AND REPAIR, *Multiuse*, Characteristics,” Section 4-101.11 states, “Materials that are used in the construction of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT may not allow the migration of deleterious substances...”³⁹ Our research has found that oftentimes lead is not found in the food product itself, but is instead in the food-contact surfaces such as pottery, spoons, straws, and wrappers, which are associated with the candy. Since the medium containing the lead does not directly being consumed regulation is difficult.

Chapter four also provides specific regulatory information on lead. Section 4-101.13 (A) states, “Ceramic, china, and crystal UTENSILS, and decorative UTENSILS such as hand painted ceramic or china that are used in contact with FOOD shall be lead-free...”³⁹ If the utensils are not lead free, the *2005 Food Code* sets limits on the amount of allowable lead (as described in Table 7):

Table 7. Acceptable Level of Lead in Utensils as Described by the 2005 US Food Code

UTENSIL Category	Ceramic Article Description	Maximum Lead Mg/L
Beverage Mugs, Cups, Pitchers	Coffee Mugs	0.5
Large Hollowware (excluding pitchers)	Bowls \geq 1.1 Liter (1.16 Quart)	1.0
Small Hollowware (excluding cups & mugs)	Bowls $<$ 1.1 Liter (1.16 Quart)	2.0
Flat Tableware	Plates, Saucers	3.0

Consumer Product Safety Act of 1972 and Lead Contamination Control Act of 1988

The Consumer Product Safety Act, implementing the duties codified in 15 USC 2051 *et seq.*, is designed to protect the public from any unreasonable risk associated with harmful products on the market.⁴⁰ The Lead Contamination Control Act (LCCA), which deals specifically with lead-lined drinking water coolers, worked synergistically with the CPSA to set a precedent in lead regulation.⁴¹ These two Acts are important for the regulation of lead-contaminated candies because of the standard they established together in how lead-contaminated items would be addressed. The CPSA's authorities to abate "imminent hazards" and to provide direction regarding "notification and repair, replacement or refund" were exercised to implement a widespread recall of lead-lined drinking water coolers.⁴² It was determined by the Consumer Product Safety Commission (CPSC), in coordination with the Environmental Protection Agency (EPA), that lead-lined tanks were to be considered "imminently hazardous consumer products," as defined by both CPSA Sec. 12 (15 USC 2061), "Imminent hazards," and the Safe Drinking Water Act (SDWA) Section 1463 (42 USC 300j-23), "Drinking water coolers containing lead" and that the recall could be enforced under CPSA Section 15(d) (15

USC 2064) and SDWA Section 1462 (42 USC 300j-22), “Recall of drinking water coolers with lead-lined tanks.”⁴³ Furthermore, the CPSA sets quality guidelines for imported products. If a product does not meet standards, it can be refused admission into the U.S.⁴⁴ The CPSA also sets penalties for those who continue to distribute products that do not comply with a consumer product safety rule. The CPSA states in section 19(a) (15 USC 2068), “Prohibited Acts” that, “It shall be unlawful for any person to manufacture for sale, offering for sale, distribute in commerce, or importing into the United States any consumer product which has been declared a banned hazardous product by a rule under this Act.”⁴⁵ This allows U.S. district courts to take action against the violators under Section 22, “Injunctive Enforcement and Seizure.”⁴⁶ Consequences arising out of the continued distribution of contaminated candies are a crucial deterrence mechanism.

Case Study

Nevada Revised Statutes

NRS 585, Food, Drugs, and Cosmetics: Adulteration; Labels; Brands, provides for authorities the means to generally control food, drugs, and cosmetics in the state of Nevada. NRS 585.300, “Adulterated food: Poisonous or insanitary ingredients” specifically provides the description under which candies identified as containing lead in some part of the product or packaging are considered adulterated. Under NRS 585.300 it states that food is considered adulterated if, “Its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.”⁴⁷ This section of the NRS provides the basis for which candies whose packaging and accessories that contain lead can be regulated. Though the lead may not

be found in the food product itself, NRS 585.300 gives sufficient footing to restrict the distribution of such candies in the state of Nevada.

Nevada Health Authorities

Within the states of Nevada there are four main health agencies: the Nevada State Health Division (NSHD), the Southern Nevada Health District (SNHD) [formerly known as the Clark County Health District (CCHD)], the Washoe County District Health Department, and Carson City Health & Human Services. NRS 439, Administration of Public Health, provides for the creation and management of the State of Nevada Board of Health and subsequent Boards of Health in the jurisdictions constituting geographical and population divisions of the state of Nevada.⁴⁸ The NSHD has authority as the Commissioner of Food and Drugs. Deputy Food and Drug Commissioners are appointed throughout the state to implement any necessary enforcement actions. Deputy Food and Drug Commissioners are appointed within the other major health agencies to enact any needed programs involving food, drugs, and cosmetics.

The Southern Nevada Health District

The SNHD has several individuals appointed as deputies for the state of Nevada. The SNHD is the health authority responsible for the Clark County area of Southern Nevada. This encompasses the municipalities of Las Vegas, North Las Vegas, Henderson, Boulder City, Mesquite, and Laughlin. They are responsible, through the Southern Nevada District Board of Health, for promulgating regulations related to the health and safety of their district. They are also responsible for implementing any necessary inspections or other enforcement activities required to maintain the health and safety of Southern Nevada's residents and visitors. For many years, the SNHD has been

aware and taken action to remove lead-contaminated candies from store shelves within Clark County communities. The majority of these initiatives were related to specific recalls of products that were verified to be contaminated with lead through the federal government's product recall processes. When notifications of recalls were issued, the SNHD sent each of their Environmental Health Specialists (EHSs) to all recognized locations within their areas of responsibility to ensure that the recall was performed and that no recalled product remained on the store shelves. There were a few notable recalls conducted between 1998 and 2002 which involved tamarind pulp/jams, tamarind candy lollipops, tamarind candy rolls, and tamarind paste candy in ceramic pots.⁴⁹⁻⁵¹ In addition, an unusual recall of lead-contaminated "chapulines (CHAP-oo-LEAN-es)," which are grasshoppers with a red chili powder coating that are considered a traditional snack food in some regions of Mexico, was enacted in late 2003.⁵² Gaining cooperation from vendors was not always easy. Some vendors, fully aware of the recall and its implications for the health and safety of the consumer, actually tried to hide product from the EHSs. In most cases, this activity was discovered, and the product was successfully removed from availability to the public. The EHSs were trained to recognize the suspect candy and to educate shop keepers regarding its risks.

Awareness and Action Increase

While recalls were being implemented locally, there was a lot of work being done to investigate the topic in other jurisdictions. Notably, a series of news stories written by the *Orange County Register* in 2004 was a culmination of investigative work that had begun in the early 1990's. Based on this work, a comprehensive cradle-to-grave view of the manufacture and distribution of these lead-contaminated candies was presented for

the public's edification.⁵³ Pressure resulting from this newfound public interest resulted in the passing of California Assembly Bill 121 (AB 121), one of the very first pieces of legislation enacted to specifically address lead contamination in candy.⁵⁴ Concurrently, nationwide interest in the topic resulted in actions being taken by the American Public Health Association (APHA), Centers for Disease Control and Prevention (CDC), the City of San Francisco, the New York City Council, the state of Illinois, the Kansas City Health Department, the Washoe County District Health Department, the Chicago Department of Public Health, and the Milwaukee Health Department.⁵⁵

Cease and Desist Order

As more information and direction from federal authorities became available, the SNHD increased its efforts to protect the consumers within its jurisdiction. Following the written advice from the APHA, CDC, CPSC, and FDA; using the example of advisories issued by Washoe County District Health Department; reviewing the results of the laboratory work done the University of Nevada, Las Vegas (UNLV) School of Public Health, and considering the conclusions drawn by the *OC Registrar* in its news exposés, SNHD's Dr. Donald S. Kwalick, Chief Health Officer and Glenn D. Savage, Environmental Health Director, implemented a strategy for a community-wide recall of lead-contaminated Mexican candy.^{53, 55-57}

On February 17, 2006, a Cease and Desist Order was issued to prevent the display and sale of certain types of Mexican candies and seasonings, which had been found to contain levels of lead considered harmful to children. The specific products that were recalled included a number of chili-based powders and salts, candies made with chili, tamarind in glazed pottery, and tamarind (with or without chili) with straws from Mexico.

The Cease and Desist Order quoted Dr. Shawn Gerstenberger, from the UNLV School of Public Health, as stating:

Research conducted by the health district and UNLV indicate unsafe levels of lead in the affected candies, and in straws, sticks and other packaging materials used in their distribution...The action to remove the candies from the area store shelves is designed to prevent potential long-term, permanent effects of lead poisoning in the children who may consume these products.⁵⁸

All candy samples tested at UNLV were also submitted for verification to independent laboratories, which confirmed our results.

Field Activities Following the Cease and Desist Order

Following the issuance of the Cease and Desist Order, a comprehensive effort was taken to locate, detain, and test more product samples. The SNHD's health permit databases were reviewed to identify local markets, especially those serving the Latino community, where these products were most likely to be distributed. At the outset of the project, a specialized team was developed to go to these markets with Dr. Keith Zupnik, EHS, acting as a liaison between the SNHD and UNLV. The SNHD Environmental Health team went into markets within the community, accompanied by UNLV representatives from the School of Public Health. While at the markets, they distributed the written Cease and Desist Order, located and removed from the shelves the suspect products, placed the products on hold, and took further samples for laboratory testing. All communication, verbal and written, was available in both English and Spanish, facilitating a smoother cooperation. In addition to efforts concentrated on likely sources, field EHSs were also surveying facilities in their areas for the targeted candy.

Dialogue with Manufacturers

During and immediately following the implementation of the Cease and Desist Order, Dr. Kwalick, Mr. Savage, Dr. Zupnik, and Dr. Gerstenberger engaged in several interactions and conference calls with manufacturers of some of the banned candies. Some of the manufacturers were U.S.-based companies operating in Mexico. Ultimately, discussions resulted in resolutions that were amicable to all parties.

Revisions of Cease and Desist Order

The initial Cease and Desist Order Broadly limited the type of candy that could remain on the shelves. During the periods of time that these candies were detained, subsequent testing was able to sort out those candies that posed a lead-contaminated hazard from those that did not. On April 12, 2006, a subsequent revision to the Order was issued. Two specific products, Tama Roca Candy with straws from Mexico and tamarind candies in glazed ceramic containers from Mexico, remained banned in Southern Nevada. All other products which were tested at UNLV's laboratory and independently verified were released for placement back onto store shelves. One key point to remember, though, is that trace amounts of lead may still be found in product packaging and in other products used by children, such as toys, food jewelry, and other articles. Because of this, the recommendation remains for vigilance whenever children are using these products.⁵⁹

Continued Surveillance

The SNHD continues to monitor imported candy, especially candies from Mexico that are at risk for lead contamination. Any recalls or warnings issued from federal government health-related agencies will be acted upon and disseminated by Clark

County's health authorities. Any information regarding lead contamination in consumer products will be shared between the SNHD and the UNLV School of Public Health.

CHAPTER 6

CONCLUSIONS

In the aftermath of the September 11, 2001 terrorist attacks, The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (The Bioterrorism Act) was passed to stop terrorists from contaminating the U.S. food supply.⁶⁰ The Bioterrorism Act allows the FDA to test and inspect food and requires foreign companies to register through the FDA and notify the federal government before exporting its foods to the U.S. However, its main goal is to prevent terrorism, not lead in food.⁶¹

Recently, the FDA has taken steps to bring public awareness to the problem of toxic candies. In 2004, the FDA issued a statement on lead contamination of products imported from Mexico. In the statement the FDA acknowledges the problem of lead in candies and warns adults not to allow children to consume contaminated candies.⁶² The FDA also issued a related statement to manufacturers, importers and distributors of imported candy.⁶³ This 2004 document mirrored an earlier letter with an analogous title sent a decade prior in 1995.⁶⁴ One of the major differences between the two was the change in the “lead in sucrose” specification from the Food Chemicals Codex (FCC), which went from 0.5 ppm, recommended in 1995 to 0.1 ppm, required in 2004. In addition, the 1995 letter focused on wrappers as one of the greatest sources of lead. This opinion was revised in the 2004 letter, which acknowledged chili powder and tamarind as primary sources. It also discussed the role of the drying processes for raw ingredients as

a cause of airborne lead contamination and the involvement of the leaching of lead from improperly glazed ceramic vessels. Based on the FDA statements, other agencies concerned with public health and safety, such as the CPSC and the Agency for Toxic Substances and Disease Registry (ATSDR), issued their own statements to inform consumers, candy manufacturers, and importers of these lead poisoning risks.^{65, 66}

Since there is such contention over international and domestic regulatory standards, one suggestion would be that companies should start policing themselves better. A spokesman for Grupo Lorena, which makes the candy Pelon Pelo Rico said, “Tuna companies that make sure dolphins are not inadvertently caught in their nets stamp their cans with ‘dolphin-safe tuna.’ Candy companies could form a ‘lead-free Candy Association’ with a similar aim.”⁴ This action by companies is highly unlikely, though. Instead, we need to establish standards for lead in wrappers, pots, straws, and spoons so that concrete, measurable limits and official and enforceable policing can exist. The standards should be based on the “weight of evidence” approach and be designed to protect the health of children under the age of six who are most likely to eat these candies (the most vulnerable population).

There is no “safe” level of lead in children. We have the knowledge and means to protect the health of children! Prevention and elimination are key factors in addressing the problem of lead poisoning. As a result, there is the urgent call for a systematic effort to control and reduce lead hazards in the environment. A multi-pronged approach between healthcare providers, community-based health and social service agencies, manufacturers and distributors of at-risk candies, and federal, state, and local government agencies must be established to address the problem of toxic candies. The ultimate goal

is the protection of children's health. If alternative measures must be taken to circumvent unnecessary bureaucracy and ensure the full cooperation of local, state, federal, and international governments, then unconventional yet viable, strategies must be considered.

In progressing toward the ultimate goal of ensuring children do not have to suffer the ill consequences of lead poisoning, the SNHD has begun a program of blood lead screenings for underinsured at-risk children. The SNHD announced that it could cover the costs of screening for the first 500 at-risk children who do not have medical coverage. The program was announced to the public through a news release issued May 3, 2006. The news release also provides encouragement for families who do have medical insurance to seek the screening test through their family doctor or pediatrician.⁶⁷ Early identification of elevated BLLs and intervention to eliminate the source of the lead will be critical steps to mitigating the damage done to individual children.

Perhaps the most realistic approach to regulating lead-contaminated candies is to form a strong collaborative relationship between researchers and public health officials so problematic candies can be identified and appropriate actions can be taken. Good science supports the social justice dimensions of public health. The responsibility of researchers is twofold. First, as researchers, we must gather sufficient scientific data (large enough sample sizes from multiple lot numbers) in order to establish a solid foundation upon which regulation is feasible. Second, we must clearly and promptly communicate the findings with public health officials versed on the applicable laws and policies that can be used to remove contaminated candies from the shelves.

In Southern Nevada we have been able to successfully regulate lead contaminated candies. By developing the protocol to use the XRF machine as an efficient and accurate

screening device, we were able to test a large quantity of suspect candies relatively quickly and cheaply. We were then able to work in cooperation with the SNHD to review the various viable paths for regulation. The SNHD was eventually able to issue a Cease and Desist Order based on our findings and our review of laws and policies. Our work has developed the framework for other universities and health districts throughout the country to work together to combat the problem of lead-contaminated candies.

The importation of lead contaminated candies into the U.S. continues unabated and, unfortunately, the health of children is put at risk. It is our hope to establish a Childhood Lead Prevention Center that will act as a centralized facility to compile, analyze, and integrate the research performed on leaded candies throughout the country. Information can be posted on the internet and be made available to public health officials, researchers, parents, and community members. This could provide them with a comprehensive database to identify, locate, remove, and/or avoid the consumption of candies that contain lead. The integration of the database will give us a comparative look into the risks posed by imported candies. The database will also aid in developing concerted strategies aimed at regulating the importation of contaminated candies and protecting the health of children through methods based on the aforementioned laws and policies summarized in Table 2. It is our hope that our research will contribute to meeting the goal of eliminating health disparities set by Healthy People 2010.⁶⁸

My investigation into leaded candies accomplished a great deal. However, proposals for future projects associated with this research abound. Looking into the leaching capability of lead from the components of the candy into the food product itself is important in order to determine under what types of environmental conditions lead has

the capacity to migrate. Also, it would be advantageous to travel to the plantations and buildings that manufacture candies to sample and assess soil, water, farming, and manufacturing processes to determine potential sources of lead. Another suggestion for a future project would be the development of a community program in which a mobile unit is used to perform on-site lead screenings and educational interventions.

APPENDIX I

PERIODIC TABLE OF THE ELEMENTS AND LEAD CHEMICAL
CONFIGURATION

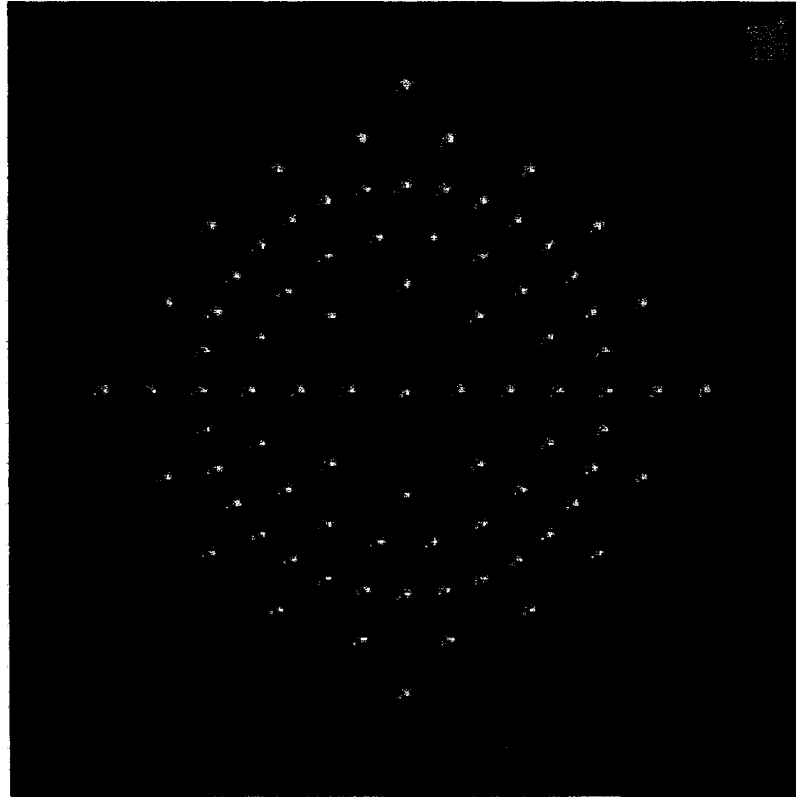
Periodic Table

1A 1 H 1.008																	2A 2 He 4.003		
										3A 6 C 12.01	4A 7 N 14.01	5A 8 O 16.00	6A 9 F 19.00	7A 10 Ne 20.18					
										15 P 30.97	16 S 32.06	17 Cl 35.45	18 Ar 39.95						
										34 Se 78.96	35 Br 79.90	36 Kr 83.80							
												53 I 126.9	54 Xe 131.3						
												86 Rn (222)							

Lanthanides [Redacted]
Actinides [Redacted]

From the CD-ROM, Animations for Introductory
 Chemistry by John I. Gelder, Oklahoma State University
 © 1994 by Oklahoma State University

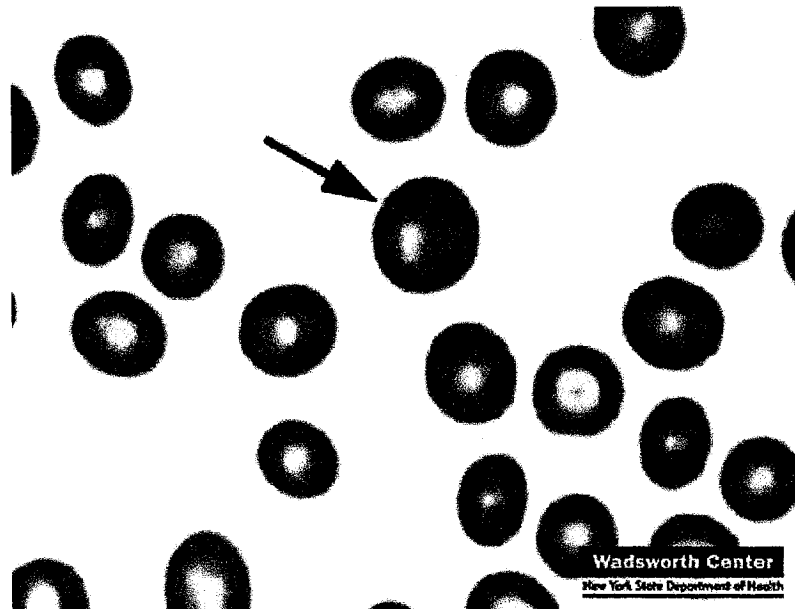
Lead is located in the blue section of the table at number 82 and is designated by the sign Pb.



The chemical configuration of lead shows where electrons are located in the orbitals surrounding the nucleus. When lead ionizes, it gives up one or more electrons to form a positively charged ion.

APPENDIX II

BASOPHILIC STIPPLING



Basophilic stippling is the premature destruction of RBCs and is characterized by purple granules that accumulate due to the inhibitory effects lead has on erythrocyte pyrimidine-5-nucleotidase, the enzyme that normally breaks down pyrimidine nucleotides.

APPENDIX III

NEPHRON

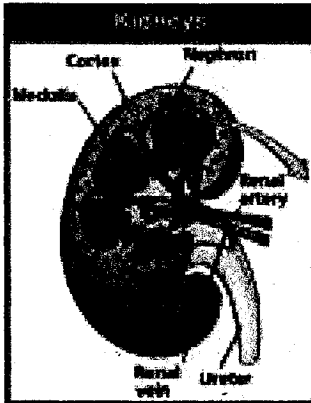


Diagram of the kidney designating the location of the nephron, cortex, medulla, renal artery, renal vein, and ureter.

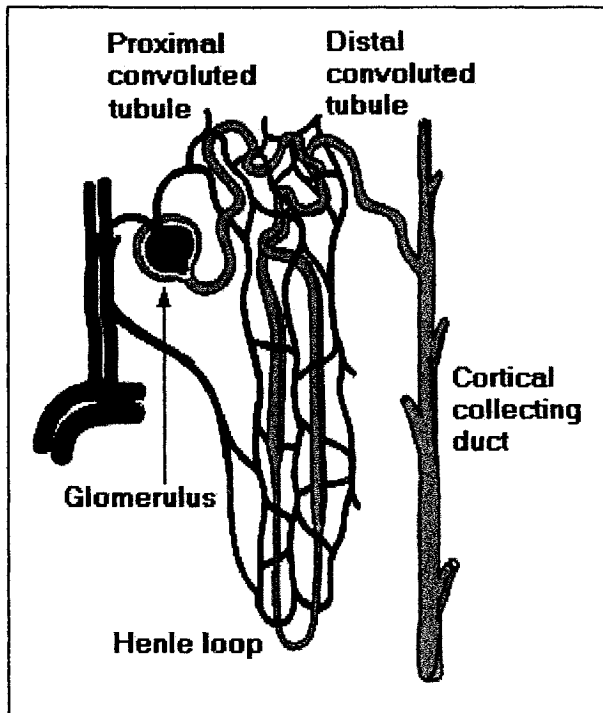


Diagram of the nephron and its components. Lead primarily targets the proximal tubule of the nephron, causing the suppressed reabsorption of glucose, phosphate, and amino acids.

APPENDIX IV

CELL BODY, AXON, MYELIN SHEATH

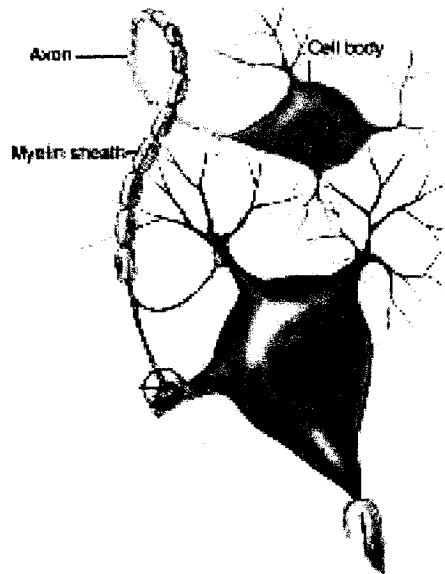


Diagram of the cell body, axon, and myelin sheath. Lead can cause the demyelination of the sheath that surrounds the neurons of the central nervous system and some of the peripheral nervous system.

APPENDIX V

ROUTES OF EXPOSURE

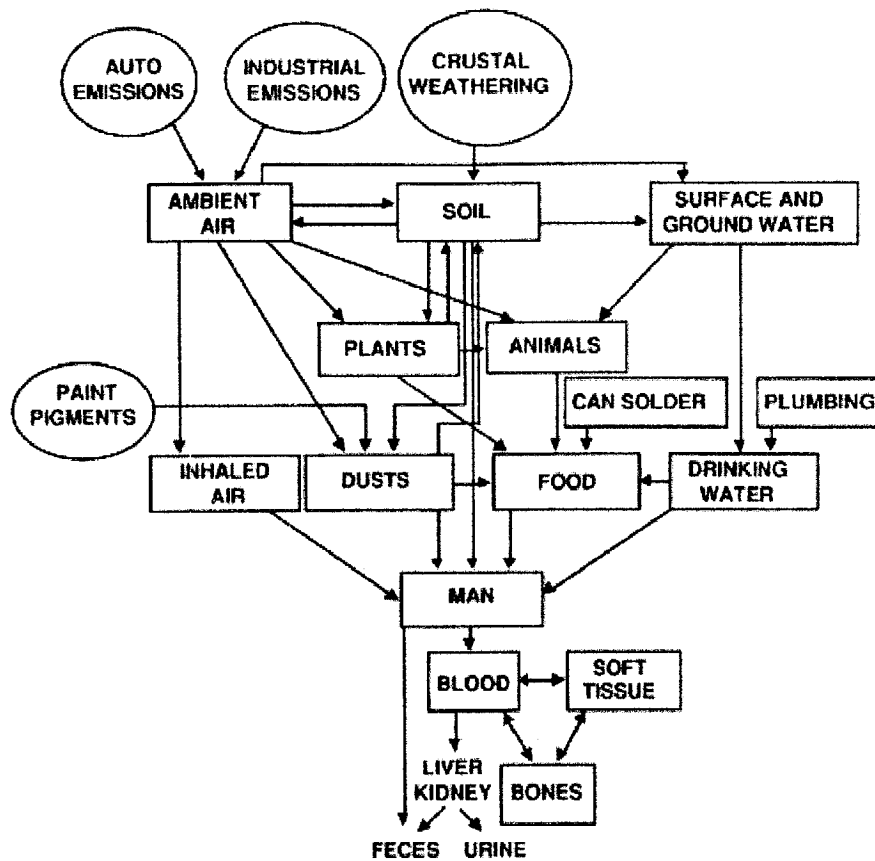


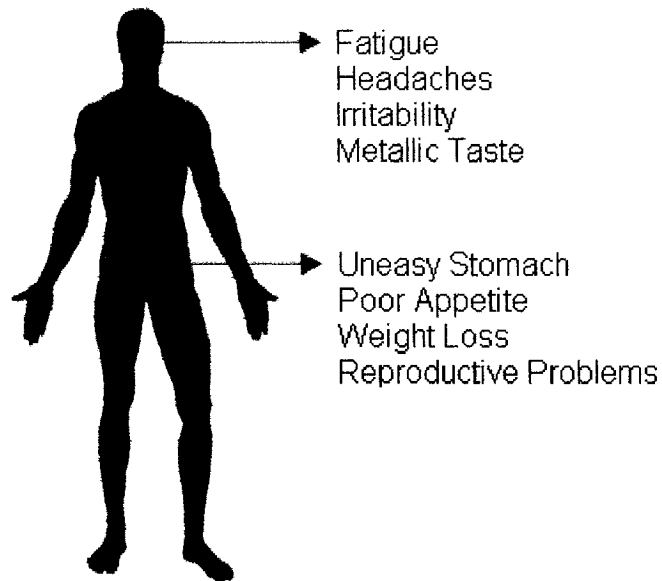
Figure 1 Pathways of lead from the environment to man, and body disposition of lead (EPA, 1986).

Pathways of lead from the environment to humans.

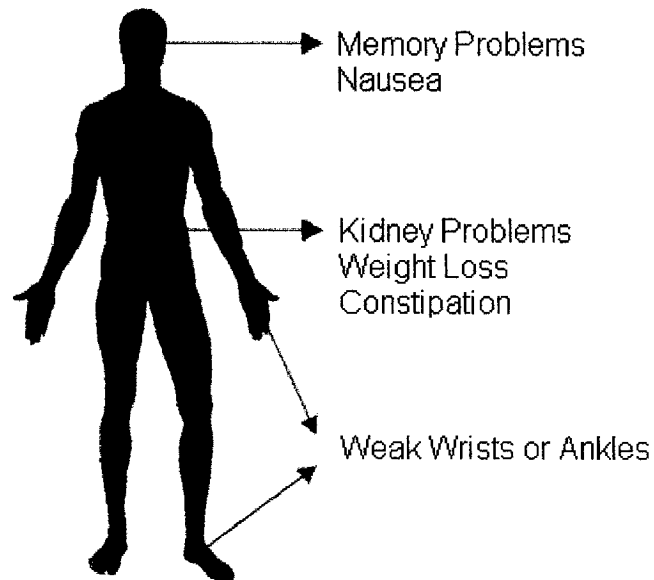
APPENDIX VI

SYMPTOMS OF LEAD POISONING

Early Symptoms of Lead Poisoning



Later Symptoms of Lead Poisoning



APPENDIX VII

“CALIFORNIA TOXIC TREAT LIST”

TOXIC TREATS

California and U.S. health officials have detected dangerous levels of lead in 112 distinct brands of candy - most of them made in Mexico. One in four candy and wrapper samples have come up high since 1993, records show. But much of this information about tainted candy has been kept from parents and public health workers.

THE ORANGE COUNTY REGISTER

Call the Register at 714-796-2289 for additional copies of this poster.

CANDIES THAT TESTED WITH DANGEROUS LEVELS OF LEAD

- 1 **Tama Roca** Tested high 28 of 143 times
- 2 **Bofirindo** Tested high 16 of 35 times
- 3 **Chaca Chaca** Tested high 17 of 38 times
- 4 **Vero Rebanaditas** Tested high 15 of 51 times
- 5 **Pelon Pelo Rico** Tested high 11 of 59 times
- 6 **Tablarindo** Tested high 11 of 60 times
- 7 **Serpentinaas** Tested high 9 of 20 times
- 8 **Vero Mango** Tested high 9 of 38 times
- 9 **Brinquitos** Tested high 8 of 12 times
- 10 **Rollito de Tamarindo (Dulmex)** Tested high 8 of 18 times
- 11 **Lucas Limon** Tested high 7 of 7 times
- 12 **Margarita Dulce de Tamarindo** Tested high 7 of 7 times
- 13 **Pica Limon** Tested high 7 of 9 times
- 14 **Lucas Acidito** Tested high 7 of 13 times

OTHER CANDIES THAT TESTED HIGH

Candy	Times Tested High	Total Times Tested
Simochewes	6	7
Vero Estrellas	5	10
High Meringues	5	5
Picantitas Brand Tamarind Candy	5	5
Limon 7	5	11
Whitots	5	18
Chaca Chaca Nictio	4	4
Licams Tamarind	4	4
Vero Super Palerindas	4	4
Ricarindo	4	5
Candy's Gum	4	13
La Colossal Dulce de Tamarindo	3	3
Arroz Fritado	3	4
Papelitas	3	6
Bolitas de Coca (Bolones)	3	6
Vero Palerindas	3	6
Be la Nasa Paleta	3	9
Pica Nana	3	12
Muebles Tasty	3	20
Vero Pica Gomas	3	27
Cachitos	2	2
Chapas LocoWays	2	2
Andy Picano	2	2
Margaritas	2	2
Starch Enchiladas Menthol	2	2
Taca Laca	2	2
Super Strawberry	2	3
Vagabonda	2	3
Alfama Obleas con Cajeta	2	4
Facterin	2	4
Welin con Chile	2	4
Muebles Tasty	2	4
Pelicans	2	4
Super Lucas Hot'n Spicy Chili Mix	2	4
Taman Zeta con Chile	2	4
Adams Family Tasty	2	5
Pelitas Azules	2	9
Pika Laca (Mismo)	2	10
Bonos Nicos	2	14
Polyparindo	2	16

*Data based on health observations on these candies. NTC (Not Tested) candies were only tested once or twice by the CDC, Department of Health Services, and the Orange County Registrar. NTC candies are not shown to save space. The complete list of tested candies can be found online at www.scrippsco.com/investigations/lead/

AVOIDING LEAD

Tainted candy is cited as a potential source of lead poisoning in Orange County nearly as often as paint, but there are numerous ways children can be exposed to lead.

IN CANDY

In wrappers
Candy wrappers are printed with inks that contain lead. The lead is hazardous because it can leach into candy, or children can lick or eat the wrappers.

In chili
Chili often is not cleaned before it is melted, so dirt, which has lead, is thrown into the mix.

In glaze
Candy is sometimes packaged in small clay pots. To give these pots a shiny look, they are covered with a glaze called *grasa*, which contains lead. Lead leeches into the candy.

In Tamarind
Tamarind is sticky, and lead from pesticides, fertilizers or dirt can attach to it.

OTHER SOURCES

Lead-based paint and lead-contaminated dust: are still the top sources of lead poisoning.
Hobbies: melting stained-glass windows.
Work: recycling or making automobile batteries.
Drinking water: lead pipes, solder, brass fixtures and valves can all leach lead.

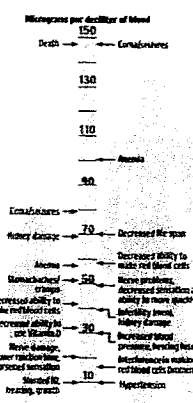
Many health remedies: ointments and syrups, which are used for upset stomach or indigestion; pay-tooth, which is used for rash or fever.

Other possible sources: ceramic pottery from other countries, dinner plates, chins painted with lead-based paint, imported silver jewelry, bicycle fender covers, children's shoes, crayons.

SOURCE: Dept. of Health Services, The Register

HOW LEAD AFFECTS YOU

Studies show that long-term exposure to lead can affect a child's developing nervous system. Health effects of different blood-lead levels in a child compared to an adult:



LEGEND: Register research graphs by Holly Dahl, The Register

WHERE TO FIND HELP

There are two basic tests that your doctor can perform. They require a phlebotomy or an intravenous blood draw.

Blood lead-level test:
- Measures the amount of lead in your blood at the present time.
- Estimates level of exposure.

Zinc protoporphyrin test:
- Shows the lead exposure over the last 3- to 4-months.
- Measures how much of the blood-forming process has been interfered with by lead.
- Measures the actual harmful effect lead has had on the body.

Information by phone and on the Internet.

California Department of Health Services/
California Childhood Lead Poisoning Prevention Branch
(916) 422-5988

California Department of Health Services Food & Drug Division. To report foods with lead sold in the United States
(916) 322-2632

National Lead Information Center
www.lead.gov/nationalleadcenter/
(800) 424-5323

ONLINE The Register's six-part investigation into lead in candy can be found on the Web at www.scrippsco.com/investigations/lead/



APPENDIX VIII

STATISTICAL ANALYSES

A)

Candy versus Component

Brand	Candy	Component
Banderilla Tama Roca	0	15
Margarita Dulce de Tamarind Clay Pot	1	13
Tamarind Plastic Pot	0	14

G=2.29, p=0.318

Candy versus Wrapper

Brand	Candy	Wrapper
Banderilla Tama Roca	0	6
Montes Super Natilla	0	35
Peccin Sour Chews	2	19
Strawberry Filled	0	11
Bob Esponja	0	20

G=6.11, p=0.191

B)

Country of Manufacture

Country	+/- Lead	
	+	-
Mexico	1	3
Brazil	1	0
Argentina	0	1

G=3.14, p=0.208

C)

Tamarind/Chili versus All Others

Type of Candy	+/- Lead	
	+	-
Tamarind/Chili	49	30
All Others	87	129

Overall $\chi^2=22.042$, $p\leq 0.001$

Tamarind Chili versus Chewy, Hard, and Lollipop

Type of Candy	+/- Lead	
	+	-
Tamarind/Chili	49	30
Chewy	56	50
Hard	11	39
Lollipop	20	30

Bonferroni adjusted $\chi^2=6.931$, $p\leq 0.034$

APPENDIX IX

APPLICABLE LAWS/POLICIES FOR REGULATION

<u>Relevant Law/Policy</u>	<u>Description</u>	<u>Reference</u>
FDA level of concern for food products	0.5 ppm considered maximum level of lead considered safe in food products	FDA (3)
NAFTA	Eliminate barriers to trade between the United States, Mexico, and Canada	NAFTA (17)
Article 712	<i>Right to Establish Level of Protection</i> <i>Scientific Principles</i> <i>Unnecessary Obstacles</i> <i>Disguised Restrictions</i>	NAFTA (19, 20, 21, 22)
Article 713, paragraphs 1 and 5	Requirement of each Party to abide by relevant international sanitation “standards, guidelines or recommendations”	NAFTA (23)
Article 714, paragraph 2	“Equivalence”—The importing Party’s “appropriate level of protection”	NAFTA (24)
Article 715, paragraph 3, part (a)	Reduction of negative trade effects	NAFTA (25)
Food Acts	Legislative efforts to uphold food quality and protect human health	Food Acts (29-36)
Federal Food and Drugs Act of 1906	Misbranding and adulteration	Federal Food and Drugs Act (29)
Federal Food, Drug, and Cosmetic Act of 1938 with significant amendments 1958 to present	Adulteration, composition of packaging, addition of substances for the purpose of increasing profit	Federal Food, Drug, and Cosmetic Act (30-33)
Lead Based Paint and Poisoning Prevention Act of 1971	Prohibits the application of lead-based paint to any drinking or eating utensil	Lead Based Paint and Poisoning Prevention Act (34)

Nutrition Labeling and Education Act of 1990	Food product labeling	Nutrition Labeling and Education Act (33, 35, 36)
<i>2005 Food Code</i>	Assist food control at all levels of the government	2005 Food Code (37, 38, 39)
Chapter Four, Section 4-101.11	Food contact surfaces	2005 Food Code (39)
Chapter Four, Section 4-101.13 (A)	Allowable limit of lead in utensils	2005 Food Code (39)
Consumer Product Safety Act of 1972 and Lead Contamination Control Act of 1988	Protect the public from any unreasonable risk associated with any product on the market; lead-lined drinking water coolers	Consumer Product Safety Act (40-46)
Nevada Revised Statutes	State of Nevada	NRS (47)
Chapter 585 Section 300	Food contact surfaces regulation	NRS (47)

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