

SOUTHERN NEVADA HEALTH DISTRICT REGULATIONS GOVERNING LEAD IN CANDY AND OTHER FOODS CONSUMED BY CHILDREN

WHEREAS, the Southern Nevada Health District (SNHD) is the public health entity for Clark County, Nevada, pursuant to Nevada Revised Statutes (NRS) Chapter 439, and has jurisdiction over all public health matters in the health district; and

WHEREAS, the Southern Nevada District Board of Health (Board) is the governing body of the SNHD, and is authorized to adopt regulations to prevent and control public health hazards and nuisances and to protect and promote the public health and safety in the geographical area subject to the jurisdiction of the health district; and

WHEREAS, lead is a naturally occurring heavy metal element whose toxicity in humans has been well documented. Lead is a toxic substance that attacks and adversely affects many different organs and body systems, including neurological, cardiovascular, renal, gastrointestinal, reproductive (greater than ninety [90] percent passes from mother to fetus), and skeletal systems. Children are more susceptible to the effects of lead toxicity than adults and no safe blood lead level in children has been determined. Lead is widely present in the environment due to its natural occurrence and human activities that have introduced it into the general environment such as the use of leaded gasoline. Because lead may be present in environments where food crops are grown and animals used for food are raised, various foods may contain unavoidable but small amounts of lead. However, foods may become contaminated with lead if they are grown, stored, or processed under conditions that could introduce larger amounts of lead into the food, such as when a root crop is grown in soil that has been contaminated from past use of leaded pesticides on that acreage. Under such conditions, the resulting contamination of the food may pose a health risk to consumers. There have been a number of cases of children with elevated blood lead (EBL) levels that have been investigated by the SNHD. Some of these investigations revealed the consumption of candy with excessive amounts of lead was an identified source of lead exposure.

WHEREAS, the Board finds that lead-contaminated products and lead-related hazards can affect the health and well being of the children residing in Southern Nevada, and finds that it is necessary to adopt Regulations Governing Lead in Candy and Other Foods Consumed by Children to prevent and control lead-related health hazards potentially originating from candy and other food products likely to be consumed by children, where lead content has been previously identified, and

WHEREAS, the Health Authority recognizes the importance of proper identification and removal of lead-contaminated products from the consumer market, with intent to reduce the likelihood of illness resulting from exposure to lead, and

WHEREAS, Nevada Revised Statutes (NRS) Chapter 585, NRS Chapter 446, NRS 439.366, and *SNHD Regulations Governing the Sanitation of Food Establishments 2010* give the health district authority to enforce laws and Regulations associated with contaminated or adulterated food and public nuisances, and

WHEREAS, the Board believes that the following Regulations are designed to protect and promote public health and safety, it does therefore publish, promulgate and order compliance within Clark County, Nevada with the substantive and procedural requirements hereinafter set forth.

INTENT AND SCOPE

Intent The purpose of these Regulations is to protect and promote the public health and safety of Clark County residents and visitors through preventive measures and timely corrections of significant public health and environmental issues related to lead exposure in children.

Scope These Regulations establish definitions; set standards for the identification, notification, and recall of candy and other food related products contaminated with lead that are likely to be consumed by children; provide for enforcement actions; and include provisions for recovery of the direct and administrative costs associated with the identification, notification, and recall of lead-contaminated food stuffs.

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Section 1

DEFINITIONS

Summary of abbreviations of terms used in these Regulations

EBL	Elevated Blood Lead
EHS	Environmental Health Specialist
°F	Degrees Fahrenheit
FDA	United States Food and Drug Administration
LOQ	Limit of quantification
µg/dl	microgram(s) per deciliter
µg/g	microgram(s) per gram
NAC	Nevada Administrative Code
NRS	Nevada Revised Statutes
ppb	Parts per billion
ppm	parts per million
SNHD	Southern Nevada Health District

As used in these Regulations, unless the context otherwise requires, the following words and terms defined have the meanings ascribed to them in this document.

- 1.1 “**Adulterated candy**” defined. **Adulterated candy** is any candy with lead in excess of 0.100 parts per million (ppm). Moreover, candy is adulterated if its wrapper or the ink on the wrapper contains any amount of lead.
- 1.2 “**Adulterated product**” defined. An **adulterated product** is either adulterated candy as defined by this section or any other manufactured food items, consumed by children with elevated blood lead levels, which contain lead in excess of 0.100 ppm.
- 1.3 “**Approved**” defined. **Approved** means acceptable to the Health Authority based on conformance with any applicable, adopted Regulations, good public health practices, and recognized industry standards.
- 1.4 “**Candy**” defined. **Candy** is any confectionary intended for individual consumption, including those that contain chile, tamarind, salt, or any other ingredient identified as posing a health risk. **Candy** also includes powdered snack mix products, containing combinations of salt, chile powder, sugar, and flavoring that are marketed to children.
- 1.5 “**Children**” defined. For the purposes of these Regulations, **children** are defined as people twelve (12) years of age and younger.
- 1.6 “**Concentration**” defined. **Concentration** means the relative content of a specific substance contained within larger mass, such as the amount of lead [in micrograms per gram (µg/g) or ppm by weight] in a sample.
- 1.7 “**Distribution stream**” defined. The **distribution stream** is the method of distributing a product within Clark County. The distribution stream may include the manufacturer, wholesaler, distributor and retailer along with any method of conveyance of a product between any manufacturer, wholesaler, distributor and retailer.

- 1.8 “**Elevated blood lead (EBL) level**” defined. An **elevated blood lead (EBL) level** is an excessive absorption of lead that is at or above a concentration in whole blood of 10 µg/dL (micrograms of lead per deciliter) confirmed by a single venous test.
- 1.9 “**Enforcement**” defined. **Enforcement** means diligent effort to secure compliance, including review of plans and permit applications, response to complaints, issuance of Notices of Violation or Hold Orders, and other legal processes.
- 1.10 “**Food**” defined. **Food** includes articles used for **food** or drink for man or other animals; chewing gum; and articles used for components of any such article.
- 1.11 “**Food and Drug Administration (FDA)**” defined. The United States **Food and Drug Administration (FDA)** is the federal agency responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe. The **FDA** also ensures that these products are honestly, accurately and informatively represented to the public.
- 1.12 “**Graphite furnace atomic absorption spectrometry (GFAAS)**” defined. **Graphite furnace atomic absorption spectrometry (GFAAS)** is a technique based on the fact that free atoms will absorb light at frequencies or wavelengths characteristic of the element of interest (hence the name atomic absorption spectrometry). In GFAAS, samples are deposited in a small graphite tube, which can then be heated to vaporize and atomize the analyte.
- 1.13 “**Health Authority**” defined. **Health Authority** means the officers and agents of the Southern Nevada District Board of Health and the SNHD.
- 1.14 “**Health hazard**” defined. A **health hazard** is any biological, physical, or chemical exposure, condition, or public nuisance that may adversely affect the health of a person.
- 1.15 “**Health-Permitted facilities**” defined. **Health-Permitted facilities** are those facilities or businesses, which have been issued a document by the Health Authority that authorizes a person to operate a business legally regulated by the Health Authority.
- 1.16 “**Hold Order**” defined. A **Hold Order** is a directive by the Health Authority to the Health Permit holder or responsible person to prohibit the use, serving, selling, or re-location from the establishment of any consumer product, including candy and other food products, which is suspected or confirmed to be adulterated with lead or any other adulterant at concentrations prohibited by law or regulation. A **Hold Order** may be vacated or released only by the Health Authority who issued it.
- 1.17 “**Inductively Coupled Plasma Mass Spectrometry (ICP-MS)**” defined. **Inductively Coupled Plasma Mass Spectrometry (ICP-MS)** is a highly sensitive analytical technique used to determine the mass of individual elements at the parts per billion level. The technique involves coupling together an inductively coupled plasma as an ion source with a mass spectrometer as a method of detecting the ions.

- 1.18 “**Lead**” defined. **Lead** is a naturally occurring heavy metal element that is widely present in the environment due to both its natural occurrence and human activities. Lead toxicity in humans has been well documented and adversely impacts many body systems. Even low exposures to lead have been shown to severely affect the development of children under the age of six.
- 1.19 “**Limit of Quantification (LOQ)**” defined. The **limit of quantification (LOQ)** is the minimum concentration or amount of an analyte that a method can measure with a specified degree of precision.
- 1.20 “**Nevada State Health Division**” defined. The **Nevada State Health Division** promotes and protects the health of all Nevadans and visitors to the state through its leadership in public health and enforcement of laws and regulations pertaining to public health. In fulfilling its mission, the **Nevada State Health Division** is guided by the State Board of Health and administers four bureaus.
- 1.21 “**Nuisance**” defined. A **nuisance** is anything, which is injurious to health, or offensive to the senses, so as to interfere with the comfort or endanger the health or safety of the public as defined by NRS 202.450.
- 1.22 “**Operator**” defined. The **operator** is the person who holds the license of a Health-Permitted or other business or is responsible for the management of such a location at the direction of the owner.
- 1.23 “**Person**” defined. The term **person** includes individuals, firms, partnerships, associations, public or private institutions, municipalities, political subdivisions of the state of Nevada, governmental agencies, or public or private corporations.
- 1.24 “**Product**” defined. A **product** is a manufactured food item that has been found to be an adulterated food or found to resemble in labeling an adulterated food.
- 1.25 “**Recall**” defined. A **recall** is a firm's removal or correction of marketed products, including its labeling and/or promotional materials, that SNHD considers to be in violation of these Regulations. SNHD can initiate legal action, for example, seizure or other administrative or civil actions available to the Health Authority if the product was not recalled. Recall does not include market withdrawal or a stock recovery.
- 1.26 “**Responsible person**” defined. The **responsible person** is the individual designated by the operator as being responsible for compliance with these Regulations.
- 1.27 “**Wrapper**” defined. The **wrapper** includes all packaging materials in contact with the candy, including, but not limited to, the paper cellophane, plastic container, stick handle, spoon, small pot (olla), straw, and squeeze tube, or similar devices. **Wrapper** does not include any part of the packaging from which lead will not leach, as demonstrated by the operator of the manufacturing facility, to the satisfaction of the Health Authority.

Section 2

SAMPLING FOR FOODS POTENTIALLY ADULTERATED WITH LEAD

2.1 Sampling for potential lead adulteration

- 2.1.1** Samples may be taken from manufacturing facilities, distribution facilities and retail outlets for testing of lead content when the Health Authority is made aware that certain foods, potentially in the Clark County distribution stream, have been identified as adulterated by other federal, state, or local entities.
- 2.1.2** The Health Authority may become aware of the potentially adulterated food during an investigation of a child with an elevated blood lead (EBL) level, where the child is reported to have consumed specific food(s) that, after laboratory testing, were found to have lead content exceeding 0.100 ppm.
- 2.1.3** At the discretion of the Health Authority, additional random sampling and testing of candy may take place at any time.
- 2.1.4** Foods sampled by the Health Authority shall be sent to a qualified laboratory that has demonstrated proficiency to conduct lead analysis using ICP-MS on food or using either ICP-MS or GFAAS on wrappers using laboratory procedures and methods outlined in the current version of the United States, Food and Drug Administration, Elemental Analysis Manual for Food and Related Products. The method employed shall have a limit of quantification (LOQ) of 50 parts per billion (ppb) or less (i.e., 0.050 ppm).

2.2 Food removal pending sample results

- 2.2.1** The remaining production lot of the sample taken pursuant to **Sections 2.1.1 to Section 2.1.3** inclusive, shall be temporarily removed from sale and distribution to retail outlets as appropriate.
- 2.2.2** The Health Authority shall issue a Hold Order for the remaining foods specified in **Section 2.2.1**, in accordance with NRS Chapter 585 and Chapter 446 (See **Appendices A and B**). This Hold Order shall remain in effect until the foods have been tested, the results have been received and reviewed by the Health Authority and the Health Authority has determined that foods are not adulterated.
- 2.2.3** For the purposes of this **Section**, if the production lot cannot be determined for the remaining food specified in **Section 2.2.1**, then all similarly-labeled foods shall be removed from sale or taken out of distribution, as appropriate, and a Hold Order shall be issued for these remaining foods in accordance with NRS Chapter 446.

2.3 Sample results

- 2.3.1** The results of any testing shall be shared with the public through the Health Authority website.
- 2.3.2** The operator of the retail outlet, distribution facility, and/or manufacturing facility shall be notified by the Health Authority, in writing, of the findings.
- 2.3.3** Any food held under a Hold Order specified in **Section 2.2.2**, which is found to be unadulterated, shall be released by the Health Authority in writing to the operator of the retail outlet, distribution facility, and/or manufacturing facility.
- 2.3.4** Any food or wrapper which the Health Authority determines to be adulterated shall be declared a public nuisance.

Section 3

REMOVAL OF FOOD ADULTERATED WITH LEAD FROM DISTRIBUTION AND SALE

3.1 Hold Order Continuance

3.1.1 Any adulterated product or wrapper which has been declared a public nuisance by the Health Authority, as determined by the sample results in **Section 2.3**; shall have the Hold Order specified in **Section 2.2** continued in accordance with NRS Chapter 446.

3.2 Issuance of Notice of Violation

3.2.1 The operator of the distribution facility, and/or manufacturing facility of the adulterated product, in addition to the operator of the retail outlet if the sample was taken from a retail location, shall be issued a Notice of Violation (NOV) of these Regulations. The NOV shall, in writing:

- 3.2.1.1** Identify the adulterated product in question and any lot numbers or other distinguishing information;
- 3.2.1.2** Specify that the operator of the retail outlet, distribution facility, and/or manufacturing facility shall continue the Hold Order of the adulterated product, until otherwise notified in writing by the Health Authority;
- 3.2.1.3** Place a Hold Order on all lots and similarly labeled products sold and/or distributed in Clark County;
- 3.2.1.4** Require all retail sales of all lots and similarly labeled products cease immediately;
- 3.2.1.5** Require an immediate recall of all products under the Hold Order specified in **Section 3.2.1.2** and **Section 3.2.1.3**;
- 3.2.1.6** Direct the destruction of the product under the Hold Order specified in **Section 3.2.1.2** and **Section 3.2.1.3**;
- 3.2.1.7** Require the operator to pay the costs associated with collecting and testing the product;
- 3.2.1.8** Any additional retail sales and/or distribution of any lots or similarly labeled products shall not occur until the products are proven to the Health Authority to be manufactured free of lead as stipulated in **Section 4.2 et seq.**;
- 3.2.1.9** Provide a name, business address, and telephone number of the Environmental Health Specialist (EHS) to contact regarding the NOV;
- 3.2.1.10** Specify the time period within which the actions must be completed.

3.3 Responsibility of Retail Operator

3.3.1 In response to the NOV, the operator of the retail outlet shall:

- 3.3.1.1 Cease all sales of product placed on hold as specified in **Sections 3.2.1.2** and **Section 3.2.1.3**.
- 3.3.1.2 Post a notice, within two (2) business days of receipt of the NOV, in a conspicuous location near where the product was sold, for no less than thirty (30) consecutive days or as otherwise specified by the Health Authority. The form and content of the notice shall be approved by the Health Authority prior to its posting.
- 3.3.1.3 If applicable, remit to the Health Authority the costs specified in **Section 3.2.1.7** within thirty (30) days of receipt of the NOV.
- 3.3.1.4 Immediately cease all additional sales of the product until the operator has received written approval from Health Authority.

3.4 Responsibility of Manufacturing and/or Distribution Facility Operator

3.4.1 In response to the NOV, the operator of the distribution facility and/or manufacturing facility shall:

- 3.4.1.1 Cease all sales of the product and commence a recall of the product found in Clark County outlets.
- 3.4.1.2 Provide the Health Authority with documentation, within two (2) business days of receipt of the NOV, indicating the amount and location of the product in distribution at the time of the recall.
- 3.4.1.3 Post a notice, within two (2) business days of receipt of the NOV, at each retail outlet, in a conspicuous location near where the adulterated product was sold, for no less than thirty (30) consecutive days or as otherwise specified by the Health Authority. The form and content of the notice shall be approved by the Health Authority prior to its posting.
- 3.4.1.4 Remit to the Health Authority the costs specified in **Section 3.2.1.7** within thirty (30) days of receipt of the NOV.
- 3.4.1.5 Immediately cease all additional distribution and sales of the product until the operator of the distribution facility and/or manufacturing facility until written approval from Health Authority has been obtained as stipulated in **Section 4.2 et seq.**

3.5 Voluntary Destruction of Product

3.5.1 Any product under a Hold Order as specified in **Section 3.2.1.2** and **Section 3.2.1.3** in accordance with NRS Chapter 446 may be voluntarily destroyed by the operator of the retail outlet, distribution facility, and/or manufacturing facility.

- 3.5.1.1** The product shall be destroyed under the witness of a representative of the Health Authority, such as an EHS.
- 3.5.1.2** Any costs incurred by the Health Authority for witnessing the voluntary destruction of the product shall be paid to the Health Authority, in advance, by the operator of the retail outlet, distribution facility, and/or manufacturing facility who is voluntarily destroying the food.

3.6 Court Ordered Destruction of Product

3.6.1 Any product not destroyed voluntarily may be ordered to be destroyed by a court of competent jurisdiction under the provisions of NRS 585.250 to NRS 585.280.

- 3.6.1.1** Restitution of any Health Authority costs including time staff spent investigating, collecting, and processing the samples and preparing any NOV or correspondence, along with all laboratory and attorney's fees shall be included in the request for a court order.

Section 4

PUBLIC NOTIFICATIONS FOR FOOD ADULTERATED WITH LEAD AND REQUESTED TESTING OF FOOD PRODUCT

4.1 Public and other notifications required

4.1.1 In addition to the signage, which is required to be posted at the location where the adulterated product has been located as per **Sections 3.3.1.2 and 3.4.1.3**; the public shall be notified by the Health Authority in the form of a press release for any occurrence where the Health Authority identified an adulterated product.

4.1.2 The Health Authority shall notify both the United States Food and Drug Administration (FDA) and the Nevada State Health Division whenever the Health Authority identifies an adulterated product.

4.2 Requested testing of products under a Hold Order

4.2.1 For any product under a Hold Order, the operator of the retail outlet, distribution facility and/or manufacturing facility may request that the Health Authority test an additional sample of the product after

4.2.1.1 The operator has provided the Health Authority with the corrective actions taken to eliminate the source of lead from the product and

4.2.1.2 The cost of any subsequent sampling and testing is borne by the operator of the retail outlet, distribution facility and/or manufacturing facility requesting the additional testing and be paid in advance of the testing.

4.2.2 The Health Authority shall select the product to be tested.

4.3 Results of additional product testing

4.3.1 If the product, following testing specified in **Section 4.2**, is found to be unadulterated, then the Health Authority shall provide the operator of the retail outlet, distribution facility, and/or manufacturing facility with a letter or other written notification that the product has been tested and determined to be unadulterated.

4.3.2 The letter or notification shall advise the operator of the retail outlet, distribution facility, and/or manufacturing facility that the sale and distribution of the product within Clark County may resume.

4.3.3 If the product is found to remain adulterated after testing specified in **Section 4.2**, the operator of the retail outlet, distribution facility, and/or manufacturing facility may submit samples in the manner specified by **Section 4.2** until such tests prove the product to be unadulterated.

4.4 Public posting of notices

- 4.4.1 The operator of the retail outlet, distribution facility and/or manufacturing facility shall not remove the notice posted as required by **Sections 3.3.1.2** or **3.4.1.3** until the specified 30 days has expired or as otherwise specified by the Health Authority.
- 4.4.2 Post a notice, within two (2) business days of receipt of the NOV, in a conspicuous location near where the product was sold, for no less than thirty (30) consecutive days or as otherwise specified by the Health Authority. The form and content of the notice shall be approved by the Health Authority prior to its posting.
- 4.4.3 The operator of the retail outlet, distribution facility and/or manufacturing facility may place an additional notice adjacent to the recall notice required by **Section 3.3.1.2** or **Section 3.4.1.3** that explains any subsequent actions taken by them and the results of any additional testing. This notice must be provided to the Health Authority prior to posting.

Section 5

NOTICES OF VIOLATION AND ENFORCEMENT

5.1 Delivery of the NOV

An NOV may be served in any of the following ways:

5.1.1 By personal service thereof upon the operator of the retail outlet, distribution facility, and/or manufacturing facility, or

5.1.2 By sending the NOV by registered or certified mail, return receipt to the operator of the retail outlet, distribution facility, and/or manufacturing facility at the last known address.

5.2 Failure to comply

5.2.1 Whenever the operator of the retail outlet, distribution facility, and/or manufacturing facility fails to comply with the NOV, relief may be sought by the Health Authority through the provisions of the *SNHD Regulations Governing the Sanitation of Food Establishments*, through a court of competent jurisdiction, through the provisions specified in NRS Chapter 585 or NRS Chapter 446, and/or a civil injunction.

5.2.2 Restitution of the Health Authority's costs for the time spent investigating the product, collecting and processing samples, and preparing NOV's and correspondence, along with all associated laboratory costs and attorney's fees will be included in the request for prosecution and/or relief.

Section 6

MISCELLANEOUS

6.1 Severability clause

Should any section, paragraph, sentence, phrase, or provision of these Regulations be held invalid for any reason, the remainder of these Regulations shall not be affected.

6.2 Effective date

6.2.1 These Regulations were adopted at a duly noticed public hearing on August 25, 2011.

6.2.2 These Regulations became effective upon approval by the Nevada State Board of Health on October 14, 2011.