

**PROTECTING CHILDREN FROM OVEREXPOSURE TO LEAD IN CANDY  
AND PROTECTING CHILDREN BY LOWERING THE BLOOD LEAD “LEVEL  
OF CONCERN” STANDARD**

The American Public Health Association:

Recognizing that in April 2004, the Orange County Register in an investigative report, published for the first time information that the state of California had been testing for lead in candies for decades but had not informed the public about the high lead levels in many candies, candy wrappers and seasonings (sold as a snack item and consumed as candy) imported from Mexico, the Philippines and other countries,<sup>1</sup> and

Recognizing, as a result of the April 2004, Orange County Register report, that various state and county environmental health practitioners, and congressional legislators have become aware of the inconsistently high lead level found in imported candies (and their wrappers).<sup>1,2</sup> Childhood lead poisoning has previously been reported as being associated with candy from Mexico,<sup>3,4</sup> and

Knowing that a significant and unnecessary health risk to Latino and other children exists when they ingest many types of imported candies containing high lead levels (both salt and sugar based). These candies are sold in United States grocery stores, in ethnic markets, in swap meets, and in street vendor stalls and carts. Many have been found to have high levels of lead,<sup>1</sup> and

Noting the United States Food and Drug Administration’s (FDA’s) lead enforcement standards on candies, made in Mexico, the Philippines and other countries and imported into the United States, fail to adequately protect Latino and other children who consume these candies, and

Recognizing the FDA has set no enforcement standards on imported salt-based candies and that the FDA treats these salt-based candies like seasonings,<sup>2</sup> and

Further, recognizing that these salt-based products are stored and marketed in containers that are attractive to children and are consumed as candies. Latino and other children can consume one or more containers of these candies per day,<sup>2</sup> and

Noting that independent laboratory test results, on samples of these salt-based candies taken from two different agencies in two different states, revealed a large variation in the lead content from one salt-based candy container to another. However, both agencies’ test results had the same mean average of 15 micrograms of lead per salt-based container,<sup>2</sup> and

Understanding that at 15 micrograms of lead, in an imported salt-based candy container, it would take a young child’s ingesting only four of these containers per day to increase the child’s blood lead level by 10 micrograms per deciliter,<sup>5</sup> and

Noting the FDA recommends a 6 micrograms per day tolerable limit for dietary intake of lead for children age 6 years or younger to prevent the more subtle adverse neurological and behavioral effects of lead exposure,<sup>5</sup> and

Realizing that consuming the contents of one of these imported salt-based candy containers in a day, containing 15 micrograms of lead, exceeds the FDA's maximum recommended daily dietary lead intake standard by 150%, and

Noting, in regards to sugar-based candy, the FDA initially stated it would, "consider action against candy products that exceed 0.5 ppm lead"; however, the FDA subsequently revised this standard stating, "it may also consider action against candy products containing 0.5 ppm or less lead, when the amount of lead per serving is 10 micrograms or more",<sup>6</sup> and

Understanding the FDA's enforcement level of 10 micrograms of lead per single serving of sugar-based candy exceeds the FDA's maximum recommended daily dietary lead intake standard by 67%, and

Noting the National Academy of Sciences' Food Chemicals Codex (FCC) specification for lead in sucrose (sugar) is 0.1 ppm.<sup>7</sup> Therefore, the standard for lead in all candy should not exceed the standard for lead in sugar, since candy, unlike sugar, is not normally diluted with other food products before being ingested, and

Noting that in 2004, the FDA issued a warning stating, "The Food and Drug Administration (FDA) is aware of the problem associated with lead contamination of some Mexican candy products being sold in the United States and is advising parents, care providers and other responsible individuals that it would be prudent to not allow children to eat these products at this time",<sup>8</sup> and

Recognizing this FDA warning is insufficient to protect children's health because it does not adequately prevent the consumption of these candies, either because parents and childcare providers elect not to comply with the FDA's warning statement or because they are unaware of the existence of this warning statement, and

Realizing that in August of 2004, Lucas®, a subsidiary of Mars Inc., announced a voluntary withdrawal of these imported salt-based candies, which are labeled as "seasonings".<sup>9</sup> However, these salt-based candies were still readily available for sale on store shelves in the United States months after the candy company announced its voluntary withdrawal,<sup>10</sup> and

Understanding the FDA should set lead enforcement standards on all salt-based candies, rather than rely on the industry to voluntarily withdraw these lead tainted candies, and

Realizing the U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of serious injury or death from more than 15,000 types of

consumer products under the agency's jurisdiction, including lead contaminated candy wrappers,<sup>11</sup> and

Knowing children will be exposed to lead from licking or eating lead contaminated candy wrappers, the U.S. Consumer Product Safety Commission sent letters to candy producers in Mexico and to candy importers in the United States informing them to halt future imports of candy until they could ensure that the candy wrappers did not contain lead or use lead containing ink,<sup>39,12,13</sup> and

Realizing that Rep. Henry Waxman (D-CA) recently introduced a bill that would direct the U.S. Consumer Product Safety Commission to adopt regulations that would ban all consumer products, including candy wrappers, used by children under age 6, that contain more than a trace amount of lead.<sup>14</sup> Knowing that preventing the exposure to lead from all sources, including consumer products, is essential to protect children from the toxic effects of lead, and

Understanding that while lead is often noted for its neurotoxicity, an elevated lead level is also a risk factor for other health problems, such as aggressive behavior, school and social failure, hearing loss, hypertension, cardiovascular disease, renal disease, and dental caries,<sup>15</sup> and

Understanding that lead and lead compounds have been recently listed as, "reasonably anticipated to be human carcinogens,"<sup>16</sup> and

Recognizing several longitudinal studies, of lead exposure and cognitive function, have found neurodevelopmental delays and reduction in IQ at even low levels of lead exposure in children.<sup>15,17,18,19,20,21,22,23</sup> This neurological damage caused by lead appears to be irreversible,<sup>15,24</sup> and

Understanding research supports the conclusion that reduction of IQ in children results when blood levels are below 10 micrograms per deciliter. The evidence clearly demonstrates the highest rates of IQ loss occur at low blood lead levels,<sup>15,23,24,25,26,27,28,29</sup> and

Recognizing that one recent study's "best estimate" of IQ losses in children is 7.4 IQ points, as the lifetime blood lead levels rise from 1 to 10 micrograms per deciliter.<sup>15</sup> However, the U.S. Centers for Disease Control and Prevention's (CDC's) "blood lead level of concern," is set at a blood lead level of 10 micrograms per deciliter or greater,<sup>30</sup> and

Recognizing a recent international pooled analysis of data, from previous studies on the effects of lead on children's intellectual function, showed an observed decline of 6.2 IQ points for an increase in blood lead levels from < 1 to 10 micrograms per deciliter. This study also concluded that blood lead levels in children < 7.5 micrograms per deciliter is associated with intellectual deficits,<sup>29</sup> and

Understanding, recent studies suggest there may be no toxic threshold limit for the adverse consequences of lead exposure.<sup>15,29,31</sup> Therefore, the current CDC's "blood lead level of concern" of 10 micrograms per deciliter should not be interpreted as a threshold for toxicity,<sup>31</sup> and

Understanding that even though the CDC Childhood Lead Poisoning Prevention Program recognized that elevated blood lead levels below the CDC's "blood lead level of concern" of 10 micrograms per deciliter can cause adverse health effects, it elected not to lower its "blood lead level of concern",<sup>23,32</sup> and

Recognizing the CDC's "blood lead level of concern" is misleading because it is actually an "action level". It is also misleading in that it implies that the significant neurological damage caused to children below this "level of concern" is not a concern of the CDC, and

Realizing that in 2002 the CDC's Advisory Committee on Childhood Lead Poisoning Prevention, which is charged with assessing scientific data and recommend changes to CDC's policy to prevent childhood lead poisoning, had its panel membership changed; replacing childhood lead poisoning experts with lead industry-connected scientists,<sup>33,34</sup> and

Realizing that the U.S. Department of Health and Human Services' regulations require clinical laboratory proficiency testing and that this testing allows laboratories to operate within a blood lead level testing error range of 8 micrograms per deciliter ( $\pm$  4 micrograms per deciliter) at the lower blood lead levels.<sup>35</sup> Understanding that this large testing error range is not warranted because at this error range it is not possible to accurately assess lower lead level toxicity occurring in children, and

Knowing the federal blood lead level testing error range is more lenient than, "external quality assessment schemes," operated in Canada and in the United Kingdom. In Canada and in the United Kingdom good laboratory performance, at a blood lead level of 10 micrograms per deciliter, is expected to be within an error range of 2 micrograms per deciliter ( $\pm$  1 micrograms per deciliter),<sup>36</sup> and

Recognizing there is no effective medical treatment for children with moderately elevated blood lead levels and the evidence supports a shift toward primary prevention of lead exposure,<sup>15,29</sup> and

Recognizing that high blood lead levels in children is still a very serious health concern. The CDC noted that during 1999-2002, among those children aged 1 through 5 years, approximately 1.6% had blood lead levels greater than or equal to 10 micrograms per deciliter,<sup>37</sup> and

Understanding that prevention is the only way to achieve the nation's 2010 health objective of reducing all young children's blood lead levels to below 10 micrograms per deciliter,<sup>38</sup> and

Understanding that lead poisoning is one of the most serious preventable pediatric health problems today, yet the vast majority of cases go undiagnosed and untreated,<sup>30</sup> and

Noting that previous APHA policy statements and resolutions do not address lead in food products (candy and their wrappers) but address lead in the environment, such as lead in paint,<sup>40-45</sup> and

Noting also that previous APHA policy statements do not address the issue of the CDC's lowering its current blood lead action level or the need to increase the accuracy of blood lead level testing, and

Recognizing that the protection of the health of children has been an expressed basic tenet of the public health profession for many years.<sup>46</sup>

Therefore, the American Public Health Association:

1. Supports the elimination of childhood lead exposure by banning all nonessential uses of lead and supports further reducing the allowable levels of lead in air emission, house dust, soil, food and water.
2. Supports Representative Henry Waxman's (D-CA) proposed federal legislation to ban lead from candy wrappers and other consumer products.
3. Supports the improvement and continual updating of the lead exposure risk-questionnaire screening guidelines to include questions on all known possible sources of lead exposure.
4. Supports the development of an aggressive prevention and education program, by public health workers, to teach the public about the dangers and effects of consuming imported candy and their wrappers with high lead levels.
5. Supports additional scientific studies to more fully understand the toxic effects of lead in children at blood lead levels below 10 micrograms per deciliter.
6. Calls on Congress to direct the FDA, in FDA's next appropriation's bill, to prioritize work on setting lead level standards for salt-based candy and reviewing its current lead level standards for sugar-based candy.
7. Calls on the FDA to set a lead enforcement standard of 0.1 ppm for all candy sold in the United States (regulating domestic and imported candy, including salt-based seasonings that are consumed as candy and which are made in Mexico).
8. Calls on the FDA to conduct sufficient monitoring of candy and to take aggressive enforcement action when its lead standards are exceeded.

9. Calls on the U.S. Consumer Product Safety Commission to strongly enforce the ban on the importation of candy from Mexico containing lead contaminated candy wrappers, as detailed in their July 2004 letters to Mexican candy manufacturers and to U.S. candy importers.

10. Calls on the CDC to substantially lower its current “blood lead level on concern” because the current action level is set too high and does not adequately protect children from the toxic effects of lead.

11. Calls on the CDC to develop intervention guidelines for children with blood lead levels < 10 micrograms per deciliter, with an emphasis on preventing all possible sources of childhood exposures to lead.

12. Calls on the Department of Health and Human Services to amend its regulatory requirement and require all laboratories, certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988, to operate with a total allowable blood lead level error of  $\pm 1$  microgram per deciliter or  $\pm 10\%$ , whichever is greater.

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<sup>2</sup> Wagner B, Sobsey R. Lead in Mexican candies and powders pose a hidden threat, Sept 22, 2004. <http://www.co.washoe.nv.us/health/> (Accessed June 16, 2005)

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<sup>5</sup> Carrington CD, Bolger PM. Division of Toxicological Review and Evaluation (HFF-156), Food and Drug Administration. An assessment of the hazards of lead in food. Regul Toxicol Pharmacol 1992;16:265-72

<sup>6</sup> US Food and Drug Administration. FDA Import Alert #33-10, Revised 4/8/04. Detention without physical examination of candy from Mexico and the Philippines due to lead.

<sup>7</sup> Food Chemicals Codex, Fifth Edition, National Academies Press, Washington, DC, 2003:455-456

<sup>8</sup> FDA statement on lead contamination in certain candy products imported from Mexico. April 9, 2004. <http://www.fda.gov/bbs/topics/news/2004/NEW01048.html> (Accessed June 16, 2005)

<sup>9</sup> Lucas® voluntarily withdraws four seasoning products from U.S. market. August 7, 2004. <http://www.ocregister.com/investigations/2004/lead/pdf/080704pressrelease2.pdf> (Accessed June 16, 2005)

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