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May 7, 2002

VIA OVERNIGHT COURIER

Food and Drug Administration
Dockets Management Branch
5630 Fishers Lane, Room 10-61
Rockville, MD 20857

CITIZEN PETITION
To Amend Title 21 of the Code of Federal Regulations,
Part 163, "Cacao Products: Standards of Identity"
To Achieve Health Protective Levels
of Lead and Cadmium in Retail Chocolate Products

Dear Sir or Madam:

On behalf of the American Environmental Safety Institute ("Petitioner"), I write to submit (in quadruplicate) pursuant to Section 505(j)(2)(C) of the federal Food, Drug and Cosmetic Act, and in accordance with 21 Code of Federal Regulations ("CFR") section 10.30, Petitioner's request that the Commissioner of the Food and Drug Administration amend 21 CFR Part 163, "Cacao Products: Standards of Identity" to establish maximum permitted levels of the toxic metals lead and cadmium in wholesale and retail chocolate products.

A. Action Requested

Petitioner requests that the Commissioner of the Food and Drug Administration amend Title 21 of the Code of Federal Regulations, Part 163, "Cacao Products: Standards of Identity," to establish that no form of cocoa or chocolate product sold in the United States of America may contain more than

- 0.02 parts-per-million of lead, and
- 0.02 parts-per-million of cadmium.

B. Statement of Grounds

Petitioner makes this request based upon the facts and law presented in the attached paper entitled "**LEAD IN CHOCOLATE: THE IMPACT ON CHILDREN'S HEALTH,**" attached as Exhibit 1 to this Petition. In summary, Petitioner establishes in this paper that most of the lead and cadmium present in wholesale and retail chocolate (and related cocoa products) is a result of man-made sources, which can and should be reduced to preclude the known and documented adverse health effects in the children and adults who consume the lead and cadmium in these chocolate products. Petitioner also establishes that the current levels

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of lead and cadmium in chocolate and cocoa products pose a clear and present health danger to consumers, especially to children under 7 years of age, based upon data from the California Office of Environmental Health Assessment, the federal Centers for Disease Control, the U.S. Department of Agriculture, and the U.S. Food and Drug Administration.

C. Environmental Impact

While an environmental assessment on the action requested in this Petition qualifies for a categorical exclusion under 21 CFR section 25.31, Petitioner's attached paper demonstrates that the proposed reduction in lead and cadmium in chocolate and cocoa products will result in significant positive impacts on the environment in cocoa bean-producing countries, for their indigenous populations, as well as for the chocolate and cocoa consuming populations, all around the world.

D. Economic Impact

Pursuant to 21 CFR section 10.30(b), economic impact information is to be submitted only when requested by the Commissioner. Petitioner will promptly provide such information, beyond that already included in the attached paper, if so requested. Please make any such request to the undersigned, who is also available to answer any questions.

E. Certification

On behalf of Petitioner, the undersigned certifies that, to the best of my knowledge and belief, this Petition includes all information and views on which the petition relies, and that it also includes that representative data and information known to the Petitioner that may be unfavorable to the Petition.

Please direct any response or inquiry regarding this Petition to the undersigned, who is also available to answer any questions.

Respectfully submitted,

THE CARRICK LAW GROUP
A PROFESSIONAL CORPORATION

By:
Roger Lane Carrick
Attorneys for Petitioner
American Environmental Safety Institute,

Attachment
RLC/kb

LEAD IN CHOCOLATE: THE IMPACT ON CHILDREN'S HEALTH
American Environmental Safety Institute
Position Paper in Support of the Attached Petition
May 7, 2002

The Problem:

Purchasing a wide variety of chocolate products available in retail stores in California, the American Environmental Safety Institute sent these unopened products for testing to a well-respected analytical laboratory, which found significant amounts of the toxic metals lead and cadmium in 68% of the chocolate products tested.

Lead has been determined by California state scientists to cause cancer and reproductive toxicity. These scientists have also determined that cadmium causes developmental toxicity. The levels of lead and cadmium present in the tested chocolate products were found by the independent testing laboratory to exceed the "no significant risk" levels set by the State of California for both lead and cadmium. Yet no chocolate product purchased and tested by the American Environmental Safety Institute carried any form of consumer warning about the presence of lead or cadmium in the product.

Based on this investigation, the American Environmental Safety Institute sent notice letters to the largest chocolate product manufacturers in 2001, asking them to reduce significantly the amount of lead and cadmium in their products. Notwithstanding good faith attempts to negotiate a resolution of the matter, these manufacturers refused to acknowledge the health threat posed by their products, and refused to lower their products' lead and cadmium levels.

As result, on May 8, 2002, the American Environmental Safety Institute filed a lawsuit against the largest chocolate manufacturers ("Big Chocolate"), under California's unique consumer environmental protection statute, Proposition 65, as well as the California Unfair Competition Act, to force Big Chocolate to warn consumers about the presence of lead and cadmium in their products. The Institute also filed petitions on May 8, 2002, with the U.S. Food and Drug Administration and its California counterpart, seeking to set new, health-protective limits on lead and cadmium in chocolate products. This position paper is written in support of those petitions.

The Analysis:

Chocolate products are among the most widely purchased consumer products in the world, with annual sales in the year 2000 reaching more than 3.3 billion pounds (valued at $8.6 billion/wholesale) in the United States alone. According to the Chocolate Manufacturers' Association, Americans eat an average of 12 pounds of chocolate products per year. Chocolate is also used as a flavoring agent in a vast array of consumer products, from ice cream to diet shakes. Children prefer chocolate snacks to all others, especially hard chocolate candies. Chocolate is marketed intensely to children, especially young children under the age of 12, with chocolate candy sales growing more than 7% per year in the late 1990's, based especially on afternoon favorites such as fun size and snack size bags of candies, which grew at a 12% per annum rate. Almost half of American adults surveyed by Gallup in 1989 called chocolate their favorite flavor.

The American Environmental Safety Institute estimates that approximately six billion units of chocolate products are purchased and consumed in the United States annually, with 900,000,000 in California alone (15% of the U.S. market), resulting in potentially 900 million violations of California's health-based Proposition 65 and related Unfair Competition Law standards annually, as well as the unknowing consumption of almost 6 pounds of lead and cadmium collectively every year by California chocolate consumers, particularly children.

Chocolate consumption, then, is a matter of significant public concern, because chocolate contains the known poisons lead and cadmium. Based on independent laboratory testing, the American Environmental Safety Institute found that lead and cadmium are present in almost every type of chocolate product tested. The levels of lead and cadmium found in these chocolate products clearly exceed California's tough, scientifically based consumer protection standards embodied in Proposition 65.

Lead and Cadmium Are Present at Significant Levels in Chocolate

Lead – The Institute's testing discovered that lead was present in 68% of the chocolate products tested (including syrup/toppings, milk chocolate products, dark chocolate products, and chocolate products that contain nuts, rice and other "inclusions"), with the levels detected in the Institute's testing starting at 0.00157 parts-per-million ("ppm") and ranging up to 0.105 ppm, showing that the amount of lead in chocolate products varies dramatically, with the highest level approximately 67 times the size of the lowest level observed in these tests.

Using an estimated daily consumption level for each type of chocolate product surveyed in the product data from each survey day in the U.S. Department of Agriculture's 1994 to 1996 "Continuing Survey of Food Intake by Individuals,"[1] the highest lead levels in these surveyed chocolate products clocked in at a daily lead exposure of as much as 4.93 micrograms per day,[2] exceeding the level permitted for lead under Proposition 65's maximum allowable dose level limit for lead of 0.5 micrograms per day (which defines significant risk as a reproductive toxicant under that statute).

Narrowing the lens of analysis, using the recommended serving levels for the following illustrative products, and using the lead levels detected via the Institute's testing of these products, their resulting daily lead consumption exposures are as follows:

- Mars M&M's 1.44 micrograms/day
- Mars Silky Dark Chocolate Dove Bar 2.11 micrograms/day
- Hershey's Special Dark Chocolate Bar 1.68 micrograms/day

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[1] This particular consumption reference point is expressly called out by the Proposition 65 regulations for both carcinogens and reproductive toxins as the appropriate consumption standard – "the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population." See 22 California Code of Regulations ("CCR") § 12721(d)(4) and § 12821(c)(2). The average consumption levels for the various types of chocolate products surveyed, including syrup/toppings, milk chocolate products, dark chocolate products, and chocolate products that contain inclusions and/or are enrobed, range from 13.5 to 44.9 grams per day.

[2] A Rocky Mountain Chocolate Factory Solid Dark Chocolate Easter Bunny weighing 155 grams and sold as a "single serving."

- Nestlé's Double Chocolate Meltdown Cocoa Drink 3.67 micrograms/day
- Kraft Chocolate Fudge Pudding 2.7 micrograms/day
- Rocky Mountain Chocolate Easter Bunny 4.93 micrograms/day.

All of these products exceed the exposures to lead permitted under the Proposition 65 limit of 0.5 micrograms per day.

Cadmium – Similarly, cadmium levels in chocolate products vary significantly as well, with the observed levels starting at 0.00215 ppm and ranging up to 0.136 ppm – here the higher level is 63 times the lower level.

Again using an estimated daily consumption level for each type of chocolate product surveyed in the product data from each survey day in the U.S. Department of Agriculture's 1994 to 1996 "Continuing Survey of Food Intake by Individuals,"[3] the highest cadmium levels present result in a daily cadmium exposure of as much as 6.12 micrograms per day, a clear violation of what the Institute believes is the proper scientific Proposition 65 "no significant risk" (as a reproductive toxicant) limit for cadmium of 0.232 micrograms per day. Using the recommended serving levels for the following illustrative products, and using the lead levels detected via testing as present in these products, their resulting daily cadmium consumption exposures are as follows:

- Mars M&M's 1.12 micrograms/day
- Mars Silky Dark Chocolate Dove Bar 2.11 micrograms/day
- Hershey's Special Dark Chocolate Bar 2.46 micrograms/day
- Nestlé's Double Chocolate Meltdown Cocoa Drink 3.67 micrograms/day
- Kraft Chocolate Fudge Pudding 2.7 micrograms/day
- Rocky Mountain Chocolate Easter Bunny 4.93 micrograms/day.

While no regulatory limit has as yet been set for cadmium ingested as a developmental toxin by the State of California, one can posit a standard, using the latest peer-reviewed research as published by the federal Agency for Toxic Substance and Disease Registry and applied under Proposition 65 regulatory regimen. Under this methodology, the proper maximum allowable dose level of cadmium by the route of ingestion is 0.232 micrograms per day, a level exceeded by all of these chocolate products.

[3] This particular consumption reference point is expressly called out by the Proposition 65 regulations for both carcinogens and reproductive toxins as the appropriate consumption standard – "the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population." See 22 California Code of Regulations ("CCR") § 12721(d)(4) and § 12821(c)(2). The levels for the various types of chocolate products, including syrup/toppings, milk chocolate products, dark chocolate products, and chocolate products that contain inclusions and/or are enrobed, range from 13.5 to 44.9 grams per day.

Lead and Cadmium Are Deadly Poisons, Especially for Children

Are these levels of lead and cadmium actually dangerous? The simple yet accurate answer is a resounding yes. Lead pollution is widely regarded as one of the primary environmental problems of the modern world.[4] Lead and compounds containing lead are highly toxic to humans, especially children – even at extremely low levels. Children are particularly sensitive.[5] Exposure to lead can come from food, water, soil, dust and smoke. Some authorities consider lead pollution to be the primary environmental problem facing the modern world. The consensus among these researchers is that no level of lead exposure is known to be free of adverse effects or otherwise "safe." As the National Research Council summarized a series of recent studies: "Those studies support the general conclusion that there is growing evidence that there is no effective threshold for some of the adverse effects of lead (*i.e.* no level below which no adverse effects occur).[6]

The U.S. Environmental Protection Agency has consistently rated lead as the second "most significant potential threat to human health" due to its "known or suspected toxicity and potential for human exposure" at hazardous waste sites.[7] Lead is among the best-documented toxic substances, whose poisonous properties have been recognized for hundreds of years.

The U.S. Centers for Disease Control ("Centers for Disease Control") considers lead poisoning the major environmental health threat to children in the United States. The Centers for Disease Control stated in 1991 that:

> Lead is ubiquitous in the human environment as a result of industrialization. It has no known physiologic value. Children are particularly susceptible to lead's toxic effects. Lead poisoning, for the most part, is silent: most poisoned children have no symptoms. The vast majority of cases, therefore, go undiagnosed and untreated.[8]

The Centers for Disease Control's 1991 report reduced the Centers for Disease Control-recommended "intervention" level for lead in children's blood from 25 micrograms per deciliter ("ug/dl") of blood, a level set in 1985, to 10 ug/dl of blood.[9]

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[4] Lead pollution has been identified as a major environmental issue by the World Health Organization, the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, the U.S. Centers for Disease Control, the federal Agency for Toxic Substances and Disease Registry, the California Office of Environmental Health Hazard Assessment, the California Attorney General, as well as leading environmental organizations such as the Natural Resources Defense Council and the group Environmental Defense.

[5] Young children have a high level of hand to mouth activity, increasing the potential for ingestion of lead-contaminated dust, soil and paint and they have a rapidly developing central nervous system, which is highly susceptible to the effects of lead.

[6] Fowler, *et al.* (eds), National Research Council, *Measuring Lead Exposure in Infants, Children and Other Sensitive Populations* (National Academy Press, 1993).

[7] "1999 CERCLA Priority List of Hazardous Substances," http://www.atsdr.cdc.gov/99list.html.

[8] *Preventing Lead Poisoning in Young Children*, U.S. Dept. of Health and Human Services, Centers for Disease Control (1991)(Introduction).

[9] "Intervention" means testing and exposure reduction efforts.

The intervention level had previously been reduced from 60 ug/dl, where it had been set in the 1950's and 1960's, to 30 ug/dl of blood in 1978. Nonetheless, the California Department of Health Services estimates that currently more than 239,000 children (7.84% of all children in California) suffer from dangerously elevated blood lead levels.

The substantial reduction by the Centers for Disease Control of the amount of blood lead that should give rise to medical intervention represents a new, dramatically lower level of an acute hazard, warranting immediate action. This strikingly lower intervention level reflects the steadily mounting research evidence demonstrating adverse health effects to children from lead exposures at very, very low levels.

By 1999, the Centers for Disease Control reported that the average blood lead level for children ages 1 to 5 in America was 2.0 ug/dl.; for children ages 6-11, the level is 1.3 ug/dl.[10] The U.S. Environmental Protection Agency has determined that for every microgram of lead that a child consumes, their blood lead level is increased by 0.16 ug/dl.[11]

Similarly, cadmium has been identified as a developmental poison, as well as a carcinogen. Cadmium is more readily taken up by plants (including cocoa trees) than any other metal, including lead. As a result, most exposures to cadmium occur through our diet. Factors contributing to the presence of cadmium in soils are fallout from air (primarily from the use of gasoline-containing cadmium or from cadmium smelting activities), use of cadmium-containing water for irrigation, and by addition of cadmium to fertilizers or as a contaminant in pesticides.[12]

Chocolate's Lead and Cadmium Levels Pose Significant Health Risks

While lead has historically affected children in a wide variety of sources, the actual consumption of lead in American children's diet has decreased in recent years.

According to the U.S. Food and Drug Administration, the primary sources of lead in children's diets in the past came from America's long-time use of leaded gasoline, lead solder in cans, and lead in house paints. Lead was banned from house paint in 1978. U.S. food canners quit using lead solder in 1991. And a 25-year phase out of lead in gasoline reached its goal in 1995. As a result of such efforts, the number of young children with potentially harmful blood lead levels has dropped 85 percent in the last 20 years, as shown in National Health and Nutrition Examination Surveys conducted by the National Center for Health Statistics. Interested in measuring the impact of lead solder's removal from food cans, the Food and Drug Administration funded collection of the data during the 1976-1980 period and has continued to support the survey efforts. The Food and Drug Administration's 1994-1996 Total Diet Studies showed that the daily intake of lead from food in 2- to 5-year-olds was 1.3 micrograms a day, while for adults,

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10 http://www.cdc.gov/nceh/dls/report/results/Lead.htm

11 "The relationship between lead ingestion and blood lead levels in children and adults has been estimated to be 0.16 and 0.04 μg Pb/dl blood per μg Pb/day ingested, respectively (EPA, 1986)." "Guidance Document for Lead in Shellfish", Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, August 1993, at V.2.1, citing U.S. Environmental Protection Agency (1986) *Air Quality Criteria for Lead* EPA-600/8-83/028aF, Research Triangle Park, N.C.

12 See generally **Environmental Contaminants in Food**, Colin F. Moffat and Kevin J. Whittle, Eds. (Sheffield, 1999), at pages 152-163.

the figure was 2.5 micrograms a day.[13] These data highlight why the focus in the 21st Century must be on more disparate sources of lead exposures than merely soldered lead cans or leaded paint, in that the lead in products like chocolate also pose a danger to children.

For example, recent scientific research has dramatically advanced our understanding of the impact of lead on the child from infant through toddler to pre-school ages. Specifically, as the U.S. Environmental Protection Agency reported in its far-ranging analysis of the health risks posed by environmental lead, a 1 sustained μg/dL increase in blood-lead concentration results in a loss of 0.257 IQ points, on average.[14]

In light of these advances in science, today we understand that children face new, more wide-ranging sources of dangerous levels of lead in their diet, including from non-nutritional sources such as chocolate. Exposures to lead in chocolate can be easily avoided, simply by not eating the product. Yet try telling that to an American child who wants a widely advertised chocolate snack. Americans must now understand that the lead in chocolate products poses a clear and present danger to their children.

Based on the science set forth above, illustrative examples dramatically drive home this point:

- a 5 year-old child consuming as little as the 1.44 micrograms in a typical snack pack of M&Ms is exposed to more lead than the average total daily lead exposure in the entire daily diet of a 5 year-old child in America today.

- Based on the blood lead level data developed by the Centers for Disease Control and the U.S. Environmental Protection Agency, the consumption of just one of these typical M&M chocolate snacks results in a 18% increase in an average 6 year old child's blood lead level.

- The consumption of a Hershey's Dark Chocolate Bar (1.68 micrograms) results in a 21% increase in an average 6 year-old child's blood lead level.

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[13] "Dangers of Lead Still Linger," *Food and Drug Administration Consumer*, January/February 1998, at http://www.cfsan.fda.gov/~dms/fdalead.html.

[14] Schwartz, J., 1993, "Beyond LOEL's, p Values, and Vote Counting: Methods for Looking at the Shapes and Strengths of Associations," Neuro Toxicology 14(2-3):237-246; Schwartz, J., 1994, "Low-Level Lead Exposure and Children's IQ: A Meta-analysis and Search for a Threshold," Environmental Research 65:42-55; Pocock, S. J., Smith, M., and Baghurst, P., 1994, "Environmental Lead and Children's Intelligence: A Systematic Review of the Epidemiological Evidence," BMJ 309:1189-1197. See also *Risk Analysis to Support Standards for Lead in Paint, Dust and Soil*, (U.S. Environmental Protection Agency (EPA 747-R-97-006) June, 1998, especially Chapters 2 (particularly at 2.3.1, which notes that "Taken together, these studies provide strong evidence that low-level prenatal or early postnatal exposure to lead results in neurobehavioral developmental delays that persist through age 5. Strong relationships between blood-lead concentration in early childhood, age 15 months to 4 years, and IQ scores were also reported, even when only slight elevations in blood-lead levels were present.") and Chapter 4. See http://www.epa.gov/lead/403risk.htm.

- The consumption of a typical Kraft Chocolate Fudge Pudding (2.7 micrograms of lead) results in a 33% increase in an average 6 year-old child's blood lead level.

- The consumption of a typical Nestlé's Double Chocolate Meltdown Cocoa Drink (3.67 micrograms of lead) results in a 45% increase in an average 6 year old child's blood lead level.

- The consumption of a Rocky Mountain Chocolate Easter Bunny (4.93 micrograms) results in a 61% increase in an average 6 year-old child's blood lead level.

Lead in Chocolate vs. Lead in Paint Chip/Dust

By way of comparison, the amount of lead from chipping and peeling lead paint (perhaps the best known contemporary hazard of lead exposure) that a child would consume from licking up all the lead in the dust in a three (3) square inch area of flooring in federal housing in Alameda County in California is only 6.15 micrograms. This amount of lead from paint chip/dust is just 47% more lead than that same child would eat in just two snack packs of M&Ms, and is **actually less lead** than that same child would get from two daily servings of Nestlé's Double Chocolate Meltdown Cocoa Drink.[15]

These comparisons demonstrate that the consumption of even small amounts of lead in these chocolate products (*i.e.*, more than one or two snacks of one of these chocolate products a day) has been shown in numerous peer-reviewed studies to have the potential to adversely affect children's IQ test performance. These conclusions are based on the same science relied upon by the US/EPA to regulate lead in everything from soldered cans to leaded paint.[16]

These numbers dramatically illustrate why the American Environmental Safety Institute's goal of protecting the public, especially children's health, via these administrative petitions is so important, and why that concern motivates the Institute's legal objective in Proposition 65 enforcement. The Institute believes and will prove in court that the consumption of lead in chocolate products contributes at a significant level to the pernicious malady of lead poisoning in American children. Certainly no one can dispute that children are among the largest, perhaps the principal focus of Big Chocolate's marketing efforts. Nor can one seriously dispute that there is a factual, empirical, *prima facie* basis for the Institute's claim that chocolate products violate Proposition 65 due to their failure to warn about the presence of significantly risky levels of lead and cadmium in these products.

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[15] See Table 3-29 on page 3-57 of the "Exposure Assessment" chapter in the U.S. Environmental Protection Agency's *RISK ANALYSIS TO SUPPORT STANDARDS FOR LEAD IN PAINT, DUST, AND SOIL* (EPA 747-R-97-006) June, 1998 (http://www.epa.gov/lead/rach3.pdf)

[16] *Risk Analysis to Support Standards for Lead in Paint, Dust and Soil,* (U.S. Environmental Protection Agency (EPA 747-R-97-006) June, 1998, especially Chapters 2 (particularly at 2.3.1, which notes that "Taken together, these studies provide strong evidence that low-level prenatal or early postnatal exposure to lead results in neurobehavioral developmental delays that persist through age 5. Strong relationships between blood-lead concentration in early childhood, age 15 months to 4 years, and IQ scores were also reported, even when only slight elevations in blood-lead levels were present.") and Chapter 4.

Big Chocolate's Defenses: The *Codex Alimentarius* Commission

With regard to potential defenses in the face of the Institute's Proposition 65 lead and cadmium exposure claims, Big Chocolate will claim that chocolate products are foods, and toxic metals in foods get a special exemption under Proposition 65. Indeed, Proposition 65 has a regulatory exemption for such toxic metals when they are naturally occurring, provided they are not a result of "human activity" (i.e., their presence in the food does not derive from the use of leaded gasoline, pesticides, fertilizers or other human sources of lead), and they are present at the "lowest level currently feasible."[17]

Big Chocolate's primary defense in this matter will likely rest solely on the argument that the documented range of lead or cadmium levels in their products is not a result of "human activity" and is at the "lowest level currently feasible" as defined pursuant to Proposition 65. However, the burden of proof pursuant to Proposition 65 lies with the would-be defendant on this defense,[18] so Big Chocolate's self-assumed burden appears quite high.[19]

What is an appropriate compliance standard by which to measure chocolate products under Proposition 65 and related statutes with regard to toxic metals in foods?

Big Chocolate may point first to the California Attorney General's endorsement of their alleged compliance with certain draft standards for lead in cocoa products currently pending before the Joint United Nation's Food and Agriculture Organization/World Health Organization's Food Standards Programme for the *Codex Alimentarius* Commission.[20]

The *Codex Alimentarius* Commission is a longstanding international food standards organization whose aim is to develop consensus standards to protect worldwide consumer health and ensure fair international trade practices. In 1994, the World Trade Organization was established, which lays out a broad framework for international trade policies. The World Trade Organization established the Agreement on the Application of Sanitary and Phytosanitary Measures, specifically recognizing the *Codex Alimentarius* Commission as the body responsible for developing international food safety standards

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17 As those concepts are used in 22 California Code of Regulations ("CCR") § 12501(a) (2) and (3).

18 Proposition 65 expressly requires the defendant to prove this claim. See California Health & Safety Code section 25249.10(c).

19 This debate has ironic historical overtones, for Big Chocolate will argue that lead and cadmium are "natural" in the same manner that C.F. Kettering of the Ethyl Corporation argued in 1925 that his breakthrough product, tetra ethyl lead (the "lead" in leaded gasoline), was so "normal" it was even found in the human body. When this question was debated in 1925 at the Surgeon General's review of the use of tetra ethyl lead in gasoline, Alice Hamilton of the Harvard Medical School presciently argued that "if this [leaded gasoline] is a probable danger, shall we not say that is going to be an extremely widespread one." Only when Professor Clair Patterson systematically argued that there was nothing normal about lead, but rather that lead was so ubiquitous as to be "typical" but certainly not "normal" did the scientific debate around the damage caused by small amounts of lead become truly scientific and result in the ban on adding lead to gasoline in the United States. See "History of Lead Poisoning in the World," Professor Dr. Herbert L. Needleman, www.leadpoison.net/general/history.html.

20 California Attorney General Bill Lockyer, in a departure from his office's usually strict health protection role, nonetheless adopted Big Chocolate's view in the fall of 2001 that these *Codex Alimentarius* Commission's draft standards should be used for Proposition 65 compliance. See the letter from California Deputy Attorney General Ed Weil dated September 28, 2001, as attached to this report.

within the World Trade Organization. However, the World Trade Organization recognizes that, notwithstanding the Agreement on the Application of Sanitary and Phytosanitary Measures, each country may determine the appropriate level of public health protection for its own population.[21]

The world's attention has been focused since the early 1980's on reducing lead exposures in cocoa, the raw material used to make chocolate. The *Codex Alimentarius* Commission acts on these issues primarily through its Committee on Food Additives and Contaminants to establish standards, maximum levels allowed for contaminants and food additive levels, as well as other standards and codes of practice. This group also sets priorities for evaluation by the Joint Expert Committee on Food Additives, the scientific advisory committee to the *Codex* Committee on Food Additives and Contaminants, for toxicological evaluations. The Joint Expert Committee on Food Additives prepares contaminant and additive toxicological monographs and is the body responsible for conducting risk assessments and setting food additive composition specifications.[22]

The *Codex* Committee on Cocoa Products and Chocolates has proposed draft maximum lead levels for the primary raw ingredients of chocolate products as follows:

Chocolate liquor:	1.0 ppm[23]
Cocoa powder:	1.0 ppm
Cocoa butter:	0.1 ppm.[24]

The *Codex Alimentarius* Commission's lead standards are controversial, in that they remain very much under discussion and intense debate. As a result, the *Codex* Commission's proposed lead standard was referred at the October 2001 meeting in Fribourg, Switzerland out of the vertical, commodity-oriented *Codex* Committee on Cocoa Products and Chocolate and re-referred to the horizontal (affecting all countries and products) Committee on Food Additives and Contaminants. The *Codex* Committee on Food Additives and Contaminants will now examine lead and cadmium levels for chocolate in the context of overall toxic metal contaminants in all foods.

The debate on reducing the lead levels in chocolate in the run-up to the Fribourg meeting of the *Codex* Committee on Cocoa Products and Chocolate was led by the Swiss delegation, which expressly noted that the lead "contamination arose from the soil and environmental pollution." This Swiss viewpoint was supported by the European Union, as well as by the United States and Australia. This perspective was opposed by Third World cocoa producing countries' delegations, lead by India and Malaysia, whose arguments were premised not on public health protection or science, but rather on the

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21 "Emerging International Contaminant Issues: Development of Codex Alimentarius standards to address the issues," U.S. Food and Drug Administration, at http://www.cfsan.fda.gov/~cjm/codexfa2.html. Originally published in *Food Safety Magazine*, February-March, 2000.

22 *Ibid.*

23 Parts-per-million, measured either as milligram per kilogram or microgram per gram.

24 These proposed lead standards are still in draft, and may yet be lowered further as a result of meetings scheduled for the summer of 2002.

cost of imposing a rigorous health-based lead standard on poorer cocoa producing countries, which could not afford such standards due to the depressed price of cocoa.[25]

On the question of cadmium, the German delegation proposed for the first time at Fribourg that the *Codex* Committee on Cocoa Products and Chocolate set a level for cadmium in chocolate and chocolate products, "in view of the fact that its information indicated the possibility of high contamination of these products resulting in considerable exposure."[26] The *Codex* Committee on Cocoa Products and Chocolate agreed to request information on proposed draft levels of cadmium for a report to the *Codex* Committee on Food Additives and Contaminants.

One must remember that these proposed *Codex* standards, even if finalized, are inherently a product of political consensus within the international community. As a result, though designed to be health-protective, these agreements are not the sort of enforceable standard required under Proposition 65 or the U.S. Food and Drug Administration.[27] In particular, as the U.S. Food and Drug Administration pointedly notes, ". . . lead has been under discussion for a long time and draft MLLs [maximum lead levels] were adopted by the CCFAC [Codex Committee on Food Additives and Contaminants] at Step 5 in 1997. The really interesting thing about developing these levels is that the exposure of adults was the reference point, never the exposure of children."[28]

Nor do they begin to differentiate between "naturally occurring" and "human activity" sources of lead or cadmium, rendering them irrelevant to the question of "lowest level currently feasible" for naturally occurring chemicals under Proposition 65.[29] As a result, one may eliminate sole reliance on the Commission's standards at the outset. However, the questions posed in the Commission's deliberations do provide guidance for further inquiry.

Human Activity in Chocolate Product Processing

The investigation undertaken by the American Environmental Safety Institute has uncovered the use of various human techniques in the processing of raw chocolate, as well as the manufacture of finished chocolate products, that may contribute to the presence of lead and cadmium in chocolate products. The Institute has also discovered that other, non-raw chocolate materials used in chocolate products contain lead and cadmium as well.

For example, the *Codex Alimentarius* Commission has approved the widespread practice of adding up to 5% processed vegetable fats to cocoa butter and other chocolate products. These vegetable fats may include everything from edible

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[25] Codex Committee on Cocoa Products and Chocolate, Alinorm01/41, "Matters Referred by the *Codex Alimentarius* Commission, para. 31, para. 28 and para. 29.

[26] *Id.*, at paras. 33-34.

[27] Even the official U.S. delegates to the *Codex Alimentarius* Commission are concerned that even if the proposed Commission's standards are adopted, they will not go far enough to reduce the amount and nature of the heavy metals present in chocolate as a result of human activity.

[28] "Emerging International Contaminant Issues: Development of Codex Alimentarius standards to address the issues," U.S. Food and Drug Administration, at http://www.cfsan.fda.gov/~cjm/codexfa2.html. Originally published in *Food Safety Magazine*, February-March, 2000.

[29] As those concepts are used in 22 CCR § 12501(a) (2) and (3).

materials like corn oil to potentially inedible or allergy-causing cotton seed oil, and even more exotic materials such as inedible oils from Sal seed, Shea, Kokum gurgi or Mango kernal. As the Indian *Codex* delegation reported in July of 2001, the use of hydrogenated vegetable fat in chocolate imported into that country resulted in highly elevated levels of the heavy metal nickel being present in the imported chocolate.[30]

The *Codex Alimentarius* Commission also approves of the widespread practice of using alkalizing and neutralizing agents in processing raw cocoa.[31] When cocoa butter has been extracted from cocoa beans, the remaining cake is finely ground into cocoa powder. When it is treated with an alkaline solution (*e.g.*, potassium carbonate), it is called Dutch-processed. The alkaline solution raises the pH level of the chocolate, which darkens the color, makes the flavor milder, and makes it easier to dissolve. In stark contrast, organic cocoa is typically non-alkaline, and this fact may explain why several (though not all) organic chocolate products that the Institute tested were lower in lead and cadmium than standard, alkalized cocoa. This alkalizing practice may potentially concentrate the heavy metal content in the alkalized cocoa, or may simply add lead from the alkalizing agent. For example, the U.S. *Pharmacopoeia* food grade for the most common agent used to alkalize cocoa – potassium carbonate – can have up to 5 parts-per-million of lead and still pass muster for use in foods, even in the United States.[32]

Furthermore, the *Codex Alimentarius* Commission's draft standard also permits the use of emulsifiers, flavoring agents, sweeteners, glazing agents, antioxidants (including butylated hydroxytoluene), bulking agents (like polydextrose A and N), and even the use of hexane as a processing aid.[33] All of these agents have been demonstrated to contain lead or cadmium as trace contaminants.

Translating The *Codex* Recommendations Into Big Chocolate's Products Shows Why They Cannot Be Used As Health-Based Regulatory Standards

Since the focus in the Proposition 65 context is on "exposure," the lead content one needs to examine is the lead in the chocolate product to which the consumer of a daily serving would be "exposed" from eating that chocolate product. Consequently, in order to consider what amount of lead the *Codex* recommendations would permit for purposes of Proposition 65 enforcement, one needs first to know how those ingredient lead tolerance recommendations would translate into actual lead levels in the finished chocolate product.

To make that translation, one must know the proportions of chocolate liquor, cocoa powder and cocoa butter that are in various kinds of finished chocolate products. The definitive, precise formulation for any given company's chocolate product will be a highly protected trade secret, in all probability inaccessible without judicially

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30 Codex Committee on Cocoa Products and Chocolate, "Proposed Draft Standard for Chocolate and Chocolate Products," CX/CPC 01/3, page 3, para. 2 (comments of India) (July 2001).

31 Codex Committee on Cocoa Products and Chocolate, "Proposed Draft Standard for Chocolate and Chocolate Products," CX/CPC 01/3, page 10, para. 3.1 (July 2001).

32 Potassium carbonate is typically made by an electrolytic-process, which is a completely man-made, not a natural, means of obtaining that material. See "Potassium Carbonate Handbook," Armand Products Company, Muscle Shoals, Alabama, especially at p.6 and *passim*.

33 Codex Committee on Cocoa Products and Chocolate, "Proposed Draft Standard for Chocolate and Chocolate Products," CX/CPC 01/3, pages 11-13 (July 2001).

enforceable discovery powers. There are, however, several kinds of publicly available approximations that provide a rough "Rosetta Stone" for translating the *Codex* ingredient standards into finished chocolate product standards.

U.S. Food and Drug Administration Standards of Identity

The U.S. Food and Drug Administration standards of identity for cacao (cocoa) products, which are set forth in 21 Code of Federal Regulations ("CFR") Part 163, provide some minimum content standards for various kinds of finished chocolate products which must be met in order to lawfully refer to the product by that designation (e.g. as a "milk chocolate," or "semi-sweet" chocolate). The regulatory minimum levels of chocolate liquor required to be in various kinds of finished chocolate products are as follows:

Semi sweet or Bittersweet chocolate: at least 35% chocolate liquor (21 CFR 163.123)

Sweet Chocolate: at least 15% chocolate liquor (21 CFR 163.123)

Milk Chocolate: at least 10% chocolate liquor (21 CFR 163.130).

The Standards of Identity tell us that in a 40 gram serving, a milk chocolate product will have at least 4 grams chocolate liquor ([40 grams times 0.10); a sweet chocolate at least 6 grams; and a semi sweet or bitter sweet chocolate at least 14 grams. Many products have substantially higher percentages of chocolate liquor. All will have an additional quantity of cocoa butter that needs to be considered. Some products will also have additional cocoa powder.

There are some publicly available descriptions of the percentages of cocoa liquor and cocoa butter that actually comprise various chocolate products. The following table sets forth these publicly known compositions of certain kinds of chocolate products.

	% Chocolate Liquor	**% added cocoa butter**	**% sugar**
Semi-Sweet or Bittersweet chocolate	35(-50)%	15%	50%
Sweet (Dark) chocolate	15%	15%	70%
Milk Chocolate	10%	20%	50%

The harder the chocolate end product, the higher percentage of cocoa butter used in that product. The chocolate product compositional information in the table above makes it possible to compute the lead tolerances which the *Codex* recommendations would permit for various typical chocolate products by applying their compositional percentages as follows: Assuming a daily serving of 40 grams,[34] and

[34] This serving size is an even-number, representative quantity. Labels vary across manufacturers,

applying the above-stated percentages, the quantity (in grams) of chocolate liquor and cocoa butter in the several kinds of finished products would be:

	Chocolate Liquor	**Cocoa butter**
Semi-Sweet or Bittersweet chocolate (35%)	14g	6g
Sweet (Dark) chocolate	6g	6g
Milk Chocolate	4g	8g

The daily-dose lead levels permitted by the *Codex* recommendations in the typical-composition products (assuming a 40gram size) can be computed by applying the ingredient tolerances (1.0 micrograms per gram for chocolate liquor; 0.1 micrograms per gram for cocoa butter) to the above quantities,[35] as follows:

Semi-Sweet or Bittersweet chocolate	14.0g (1 ug/g) + 6.0g (.1 ug/g) = 14.6 ug lead[36]
Sweet (Dark) Chocolate	6.0 g (1 ug/g) + 6.0g (.1 ug/g) = 6.6 ug lead
Milk Chocolate	4.0g (1 ug/g) + 8g (.1 ug/g) = 4.8 ug lead

Codex-Recommended Lead Tolerances Versus Current Lead Levels

The American Environmental Safety Institute's testing data shows that **the *Codex* proposed standards would increase the lead allowed in chocolate products beyond what is in those products now**. For example, for the tests taken on milk chocolate products, the detected measurements ranged from 0.020 to 0.098 ppm (a spread of over 400%), and averaged 0.036 ppm. For a 40 gram daily serving, the average measured lead level would be 1.44 micrograms. The *Codex* lead allowances would be 4.80 micrograms – more than three times as much lead permitted as compared to the current milk chocolate product average.

For sweet (dark) chocolate, the test data ranged from 0.025 to 0.142 ppm (a spread of 500%), with an average of 0.049 ppm. For a 40 gram daily serving, the average measured lead level would be 1.96 micrograms. The *Codex* recommendations again would allow over 6.6 micrograms, more than three times as much lead as compared

products and sizes. In other words, two milk chocolate bars of the same type may have different amounts of grams and each be regarded as one serving. A popular size of Hershey's bars is 1.45 oz, which is 41 grams. A popular sized bag of M&M's has 47.91 grams.

[35] Higher quality chocolate products usually have higher than average percentages of chocolate liquor and cocoa butter, and lower percentages of sugar and other-fat substitutes for cocoa butter. The *Codex* recommendations would permit such products to have more lead than those of more typical composition that are charted here.

[36] "ug/g" is microgram per gram.

to the current industry average. These comparisons in tabular form (for a 40 gram daily serving) are as follows:

	Facial Prop 65 Level	**Current Industry Ave**	***Codex*-Allowance**
Sweet/Dark Chocolate	0.5ug	1.96ug	6.60ug
Milk Chocolate	0.5ug	1.44ug	4.80ug
Enrobed Milk Chocolates	0.5ug	0.92ug	4.80ug

For semi-sweet morsels, the Institute has actual test measurements of lead for Hershey's chips, Nestlé's chips and for a generic chips product. Those measurements are as follows: Hershey's: 0.087 ppm; Nestlé's: 0.048 ppm[37]; Generic chips: 0.037 ppm. Since the actual daily serving amount of such chips may well be smaller than for chocolate bars, M&M's and the like, to be conservative a daily serving of 20g will be used. That would yield the following daily lead levels:

	Measured Lead	**Prop 65 Allowance.**	***Codex* Allowance.**
Hershey's Semi-Sweet	1.74ug	0.50ug	7.3ug
Nestlé's Semi-Sweet	0.96ug	0.50ug	7.3 ug
Generic Semi-Sweet	0.74ug	0.50ug	7.3ug

The disparities for other types of chocolate products will be comparable. As shown, the *Codex*-recommended levels would significantly increase the amount of lead permitted in comparison to the facial standard of Proposition 65 and even compared to average current chocolate product levels. Some 50% of the various chocolate manufacturers' products tested are now below the reported averages, which are in turn well below the *Codex* levels. Consequently, the *Codex*-permitted lead levels are well above the lead levels that are currently feasible.

Incorporating the *Codex*-recommendations as the determinant of the lead levels permitted in finished chocolate products would be a major step backward in terms of reducing lead exposures in chocolate products. No surprise that Big Chocolate likes the draft *Codex* standards.

[37] Hershey's significantly higher lead level on a clean, direct, comparable product match-up would seem to deflate any "feasibility" defense, as would measurements showing its products' lead levels to be no better than the industry average.

Lead and Cadmium in Chocolate: Natural or Human in Origin?

By way of background, although lead exists naturally on Earth due to geological activity, lead concentrations in the environment have increased markedly for several centuries due to human activities, including mining and smelting of ores, the combustion of fossil fuels and the dissemination of lead through industrial processes.[38] However, the most significant release of lead into the global environment was the use of tetra ethyl lead as an anti-knock additive to gasoline, which caused the atmospheric concentrations, long-range transport and deposition of lead to increase by several orders of magnitude over the past 70 years.[39] According to the National Research Council, people in the United States have average body burdens of lead approximately 300 to 500 times those found in our prehistoric ancestors.[40]

Professor Jerome O. Nriagu has shown that, through a global assessment of atmospheric trace metals, lead as an environmental pollutant is essentially of anthropogenic origin – that is to say, caused by human action.[41] Other investigators note pointedly that the current federally "acceptable" level of lead in children's blood is 10 ug/dl, which is about 625 times higher than the 0.016 ug/dl level found in the bones of pre-Columbian inhabitants of North America.[42]

As a result of these types of analyses, Big Chocolate's defense of genuinely "naturally occurring" begins to lose credibility quickly.[43] First, for example, the amounts of lead and cadmium discovered in chocolate tend to be higher than those present in other plant sources of human food (*i.e.*, vegetables and tea) grown in comparable soils, or even in meats from animals pastured on such soils.[44] Second, knowledgeable sources (like the official U.S. representative to the *Codex Alimentarius* Commission) point to the use of lead and cadmium-containing fertilizers, pesticides, and especially leaded transportation fuels in the countries where the raw chocolate materials are grown as more likely candidates than native soil conditions as sources for the lead and cadmium present in chocolate. Even the cocoa industry does not dispute this

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[38] Patterson, C.C., 36 *Am. Antiq.* 286-321 (1971); Patterson, C.C., 25 *Econ. Hist. Rev.* 205-235 (1972).

[39] Nriagu & Pacyna, 333 *Nature* 134-139 (1988); Chow & Johnstone, 147 *Science*, 502-503 (1965); Murozomi, Chow & Patterson, 33 Geochim. Cosmochim Acta 1271-1294 (1969).

[40] National Research Council, *Measuring Lead Exposure in Infants, Children, and Other Sensitive Populations* (Washington D.C.; Nat'l. Academy Press, 1993) p. XII.

[41] Nriagu, *Natural Sources of Trace Metals in the Atmosphere* 338 Nature 47-49 (1989).

[42] A. Russell Flegal and Donald R. Smith, *Lead Levels in Pre-Industrial Humans*, New England Journal of Medicine, Vol. 326, No. 19 (May 7, 1992) pp. 1293-1294).

[43] The historical echo is interesting. Compare Big Chocolate's arguments to those of the Standard Oil Company in defense of the then-revolutionary "leaded gasoline" in 1925: "Now as a result of 10 years research ... we have this apparent gift of God of three cubic centimeters of tetraethyl lead [which will allow cars to travel 50 to 100 percent further on a gallon of gasoline.] It would be an unheard-of blunder if we should abandon a thing of this kind merely because of our fears." Testimony by Frank Howard, Standard Oil Company, before the Public Health Service's inquiry on the health effects of tetraethyl lead on May 20, 1925.

[44] *Food Addit* Contam 1994 May-Jun; 11 (3): 351-63; *Nahrung* 1987 (5-6):635-6. See also Van Assche, F.J. and Ciarletta, P., (1992) "Cadmium in the Environment: Levels, Trends and Critical Pathways, Edited Proceedings Seventh International Cadmium Conference – New Orleans," Cadmium Association, London.

conclusion, for as the International Cocoa Organization notes on its Internet site, fertilizers are likely sources of lead and cadmium in cocoa beans.[45]

One must remember that cocoa beans are sold as commodity products, with the beans produced in any given national market sold through that national market onto the international cocoa bourses. As a result, a chocolate product manufacturer purchases bulk lots of beans from various national productions from an international marketer of cocoa. Then the essence of the chocolate product manufacturer's art is applied, for it is in the blending of various grades of chocolate by-products (*i.e.*, cocoa butter, cocoa cake, cocoa mass) from various types of raw cocoa beans from the West African, Southeast Asian and Latin American national markets that a specific type of chocolate obtains its unique flavor, mouth-feel and texture. Or as Hershey describes it on their website, "Cocoa beans from different countries each have a distinct flavor. After arriving at the factory, the beans are stored by country of origin until they are blended to give them that special Hershey taste." As a result, a given finished chocolate product may contain raw chocolate materials from any number of national markets (though the American Cocoa Research Institute reports that 70% of all cocoa beans are produced in West Africa). In short, one apparently does not make typical finished chocolate products from only one type of cocoa bean.[46]

Objective U.S. federal government representatives note that only the chocolate companies are likely to know the actual varying toxic metal contributions of these different cocoa bean sources, yet these same chocolate companies have refused in the past and continue to refuse today to disclose what they know as to the role of these specific sources of toxic metals to the U.S. Food and Drug Administration or to the *Codex Alimentarius* Commission. Whether some or all of this lead and cadmium in finished chocolate products is present as a result of naturally occurring or human activity sources can be obtained and vetted through deposition and document discovery in litigation, accompanied by court-supervised appropriate sampling and related tests, which the Institute will do through its lawsuit. As a result of such inquiry, one can determine the presence of lead and cadmium present at each stage of the finished chocolate product production process, permitting one to narrow the likely source of contamination (unless lead and cadmium are added as intentional ingredients in the manufacturing process, a conclusion that is unlikely but can never be ruled out).[47]

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45 See http://www.icco.org/questions/cadmium.htm.

46 However, recently some chocolate manufacturers have attempted to create a market for "estate chocolates," which are chocolates made from cocoa beans harvested from the same, limited set of trees, not blended from beans produced in various countries. See the products offered at http://www.originalhawaiianchocolatefactory.com/estate.html.

47 One observer suggests that the use of galvanized containers used in the processing of the raw chocolate materials may be responsible. *Nahrung* 1987 (5-6):635-6. Other documented uses of contaminated containers include the use of jute bags treated with waste oil. "Nigerian cocoa farmers must stop using jute bags treated with hydrocarbon if they are to avoid their commodities being rejected by European buyers, a senior industry official said Friday." *Dow Jones Newswire*, "Nigerian Farmers Warned to Halt Use of Hydrocarbon Bags," August 31, 2001. Cocoa beans are fermented in the open air, in wooden troughs that hold up to two tons of beans, and blown dry in open-air buildings using hot air pipes, locations that permit direct impact from pesticides and known aerial deposition of lead and cadmium from the use of leaded gasoline.

How extensive is the use of fertilizers, pesticides, and leaded transportation fuels in the countries where the raw chocolate materials are grown? Based upon basic research that is openly available, the answer is – quite extensive. The American Environmental Safety Institute looked at each of these potential sources in turn, starting with fertilizer.

The Source of Lead/Cadmium in Chocolate Products: Fertilizer

Fertilizers have historically been used extensively on cocoa trees, the plant from which the cocoa bean is harvested. According to the knowledgeable Cocoa Research Institute of Ghana,[48] historical use of organic fertilizers (animal and human wastes, agricultural refuse, including cocoa tree leaves and cocoa nut husks) in Africa came under increasing review in the last ten years precisely because of their known potential for concentrating heavy metals such as zinc, lead and mercury. The use of man-made inorganic fertilizers in Africa, according to the Cocoa Research Institute of Ghana, has increased in the post-World War II period, with their use fluctuating inversely with their international price. The Cocoa Research Institute of Ghana estimates that fertilizer represents almost 32% of the annual costs incurred by African cocoa growers.[49]

The actual volume of fertilizer used in cocoa nut production is harder to estimate. The International Fertilizer Association estimated in May of 1998 that cocoa and related crops accounted for 3% of all fertilizer used worldwide. In more developed countries that produce cocoa beans, such as Malaysia (where statistics are also more readily available), the authoritative Malaysia Cocoa Association estimates that the use of fertilizer on cocoa bean trees is roughly 250 kilograms per hectare of cultivated cocoa trees per year. Estimates by both the Cocoa Research Institute of Ghana and industry researchers in Canada have concluded that African cocoa bean trees will continue to decline in productive value without increasing amounts of fertilizer being applied annually, primarily because cocoa beans contain a significant amount of phosphorus, drawn from the soil.[50] Phosphorus is a primary material added to any man-made inorganic fertilizer, and must be added back to the African, Latin American and Asian soils to restore the phosphorus drawn up by the cocoa bean tree for deposit in its beans.

American efforts in Jamaica in 1996 to spur recultivation and planting of new cocoa trees found that significant use of fertilizer was required to achieve world-scale levels of production, which are critical to achieving production levels of cocoa beans that are profitable.[51]

The government of Nigeria announced in August of 2001 that it was going to subsidize 25% of all cocoa tree fertilizer costs to jump-start domestic production of

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48 "Towards an Integrated Pest Management for Sustainable Cocoa Production in Ghana," Beatrice Padi and G.K. Owusu, Cocoa Research Institute of Ghana, PO Box 8, Tafo-Akim, Ghana (see also http://natsoo.si.edu/smbc/Research/Cacao/padi.htm).

49 *Id.*

50 *Id.* and Global Transfer of Phosphorus in Fertilizer Materials and Agricultural Commodities, James D. Beaton, Terry L. Roberts, Ed H. Halstead and Lyle E. Cowell, Potash & Phosphate Institute of Canada (1995, John Wiley & Sons Ltd.)

51 U.S. Agency for International Development, Evaluation No. 55, "Agriculture and the Environment: In Jamaica, A Study in Contrasts," March 1996.

cocoa beans, and to cut-down on smuggling of cocoa beans out of the country for sale elsewhere in Africa.[52]

The potential that third-world producers of cheaply priced fertilizers will spike their fertilizer products with heavy metal waste contamination is also well known. In the United States alone in 2000,[53] imports of one People's Republic of China manufacturer of a popular zinc sulfate fertilizer totaled 1.3 million pounds of product tainted by up to 110,000 ppm of cadmium, likely derived from illegal hazardous wastes mixed into the fertilizer. Third world consuming countries like the Ivory Coast, Ghana and others will be inclined to import such cheap fertilizers over more expensive Western products, thus exposing themselves to such unscrupulous practices, and providing a clear human activity source of heavy metal contamination beyond even regular fertilizer problems.

This discussion provides ample proof of the use of both traditional organic and manufactured fertilizers in the cultivation of cocoa trees. The likely build-up of toxic metals from the use of fertilizers in the soils in which cocoa trees are cultivated is substantial. The probability that a significant fraction of the lead and/or cadmium present in the raw chocolate materials is derived from such fertilizer use is thus easily demonstrated.

The Source of Lead/Cadmium in Chocolate Products: Pesticides

The use of pesticides in the cultivation of cocoa beans is documented throughout the cocoa-producing countries. Leaded arsenate pesticides were used extensively in cocoa bean production in the immediate post-World War II period, and their adverse impact on cocoa and other human foodstuffs was first evaluated at the Joint Meeting of the United Nation's Food and Agricultural Organization ("FAO") Working Party of Experts and the United Nation's World Health Organization ("WHO") Expert Committee on Pesticide Residues, which met in Geneva, 9-16 December, 1968. The build-up of lead (and likely cadmium as well) in the soils where leaded arsenate pesticides were used was well-documented at that meeting. Cocoa producers also used Lindane and other pesticides that consistently were found as residues in cocoa products as recently as 1991.[54] These types of hexachlorocyclohexane isomers are notoriously contaminated with toxic metals in the technical grade formulations that are used as pesticides, and as a result are likely sources of lead and cadmium in cocoa raw materials.

But by far and away the largest likely source of lead and cadmium comes from the historic and continuing contemporary use of insecticide/fungicide applications of cuprous oxide and related copper oxide products (*e.g.*, Copper Sandoz). These chemicals are the weapons of choice against cocoa tree pests such as mirids and capsids, sucking insects that are one of the three principle diseases that are the scourges affecting cocoa in Ghana, Nigeria and the Ivory Coast, Africa's primary cocoa growing regions. The other two problems are the swollen shoot virus disease transmitted by mealy bugs,

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52 "The Government To Revamp Cocoa Industry," *The Guardian* (Lagos), posted to the Web on August 3, 2001.

53 *Seattle Post-Intelligencer*, "High Levels of Cadmium Found in Fertilizers," Wednesday, May 24, 2000 (http://seattlep-i.nswsource.com/national/cad24.shtml).

54 FAO/WHO Joint Report (1978); "Environmental Health Criteria 124: Lindane," WHO, Geneva, 1991. The Institute is now looking into the possibility that these pesticides may still be present in raw chocolate materials, and thus also present in finished chocolate products.

and the black pod disease caused by *Phytophthora palmivora* and the more virulent and recently introduced *P. megakarya*. In Latin America, these problems exist along side the mal de machete or the Ceratoycystis wilt of cacao, caused by a host-specialized form of *Ceratocystis fimbriata* (a disease native to Latin America). Other Latin American problems include the *Moniliophthora* pod rot caused by *Moniliohphtora rorei*. Finally, there is the most notorious current malady affecting cocoa trees, the so-called "witches' broom" that seems to affect all parts of the cocoa tree.

For each and every one of these cocoa tree insect and/or fungus problems, the standard historical and current remedy of choice use is treatment of the cocoa tree and/or bean with copper oxide-based insecticides and fungicides. Applied in very significant amounts (*i.e.*, up to 18 grams of commercial product per tree, repeated monthly for up to six months),[55] these materials have been used for more than thirty years in cocoa production. The goal of the primary program (CABI) to investigate and promote Integrated Pest Management and related non-chemical techniques in cocoa-growing regions is to eliminate the use of copper oxide pesticides.[56] Yet the Cocoa Research Institute of Ghana reports that 15% of all costs incurred in the cultivation and production of cocoa is for pesticides, documenting their continuing use.[57]

Copper oxide chemical preparations are also notorious for containing heavy metal contamination in their technical grades, the very grades purchased and used on cocoa trees to treat these diseases. The likelihood that such chemicals are the source of the lead and cadmium directly on the cocoa bean, as well as a result of the cocoa tree's metabolism from soils treated directly or indirectly with copper oxide chemical preparations, is remarkably high.

Source of Lead in Finished Chocolate Products: Leadcd Gasoline

The historic use of leaded gasoline in the third world, including most of the major cocoa bean producing counties, continues to this very day. The practice of using "back-pack" internal combustion engine applicators for both fertilizer and pesticide applications requires the use of leaded gasoline. The Cocoa Research Institute of Ghana estimates that more than 5.6 liters of leaded gasoline is used per every 1,353 kilograms of cocoa beans harvested, meaning that more than 1% of the costs of the cultivation and production of cocoa is dedicated to the purchase of leaded gasoline for these spraying devices.[58]

The official U.S. Food and Drug Administration delegate to the *Codex Alimentarius* Commission also points to the practice of drying cocoa beans beside heavily-trafficked roads for ease of pick-up and shipment exposes cocoa beans to aerial

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55 "Chemical and Phytosanitation Control of Witches' Broom for Cocoa," W. Martin Aitken, Almirante Centro de Estudos de Cacau, Barro Preto, Bahia, Brazil (a paper presented at the workshop "Current Knowledge and Programs on Witches' Broom Control" sponsored in 1997 in part by the American Cocoa Research Institute.

56 CAB International is a not-for-profit intergovernmental organization with more than 40 member countries dedicated to fostering sustainable development for small farmers. See http://194.131.255.8/Acc/ACC.htm.

57 "Towards an Integrated Pest Management for Sustainable Cocoa Production in Ghana," Beatrice Padi and G.K. Owusu, Cocoa Research Institute of Ghana, PO Box 8, Tafo-Akim, Ghana (see also http://natsoo.si.edu/smbc/Research/Cacao/padi.htm).

58 *Id.*

lead deposition from vehicular traffic using the same leaded gasoline. The paper and jute bags into which beans are transferred from the cocoa trees, and then after which they are placed for fermentation and heated, are all stored beside or close to roadways and thus susceptible to the aerial lead deposition from vehicular traffic using the same leaded gasoline. These packing materials are also transported in trucks using leaded gasoline, further exposing them to lead deposition.

The bottom line is that the use of leaded gasoline pervades the entire structure of cocoa production, from harvesting to processing to delivery for export. The potential for the aerial deposition of lead onto soils, cocoa beans and their packing materials from the use of such leaded gasoline is very high.[59]

Collectively, these "human activity" sources of lead and cadmium are documented and verifiable, not just through the type of basic research set forth above, but through chemical testing techniques available in modern analytical laboratories. These tests can be used to "finger-print" these sources. The question will then ultimately be how much, not whether, "human activity" accounts for lead and cadmium in chocolate.

"Lowest Levels Currently Feasible"

As previously noted, lead is present in a wide number of finished chocolate products (including syrup/toppings, milk chocolate products, dark chocolate products, and chocolate products that contain inclusions and/or are enrobed), with the levels starting at 0.00157 parts-per-million ("ppm") and ranging up to 0.105 ppm, showing that the amount of lead in chocolate products varies dramatically, with the highest level approximately 67 times the size of the lowest level observed in these tests. Cadmium levels in finished chocolate products vary significantly as well, with the observed levels starting at 0.00215 ppm and ranging up to 0.136 ppm – here the higher level is 63 times the lower level.

This dramatic range of lead and cadmium levels is the primary indication that the levels of both lead and cadmium can be reduced, for clearly some manufacturers of finished chocolate products have significantly lower levels of lead and/or cadmium than do others. Both Mars and Hershey produce many finished chocolate products that are not at the lowest end of the range of these empirically observed lead concentrations.

For example, comparing the lead levels in two comparable products, Hershey's Semi-Sweet Chocolate Chips to Nestlé's Semi-Sweet Morsels, the American Environmental Safety Institute's testing found that the Hershey product has a lead level of 0.048 ppm, as compared to Nestlé's 0.024 ppm, a difference of exactly 100%. If Nestlé can obtain raw chocolate on the international market and manufacture a finished chocolate product with one-half the level of lead in a comparable Hershey product, then clearly Hershey is not producing its finished chocolate product containing naturally occurring lead at the "lowest levels currently feasible."[60]

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[59] The California Attorney General's office has regarded the documented use of such leaded gasoline as a non-naturally occurring source of Proposition 65-listed chemical contamination in a variety of exposures in its own Proposition 65 enforcement efforts.

[60] The California Attorney General has consistently taken the position in Proposition 65 litigation that such evidence of one consumer product manufacturer's ability to minimize lead exposures from naturally occurring foods in the consumer product can be used to force another manufacturer of the same consumer product to reduce their higher levels of lead present in that manufacturer's competing consumer

Furthermore, the proposed lead limits of the *Codex Alimentarius* Commission under debate in the fall of 2001 in Switzerland remain drafts for discussion at the on-going meetings of the *Codex* Commission. Indeed, the current debate is about revising levels of lead not addressed in final, binding form since 1983. No one attending the Commission's meetings from the United States, with the possible exception of the two representatives from Mars and Hershey, respectively, believes the existing lead standard is currently protective of human health. Rather, the official attendees from the U.S. Food and Drug Administration believe that much greater scrutiny of non-natural lead in chocolate is necessary.

A reasonable observer of the *Codex* Commission's process will recognize that the Commission's new lead limits, if and when established, are absolute in nature, and do not discriminate between "natural" and "human activity" lead. As a result, the American Environmental Safety Institute submits that the *Codex Alimentarius* Commission's draft standards on lead cannot on their face constitute "the lowest level currently feasible," as that phrase is used in 22 CCR § 12501(a) (4), for that phrase applies only to "naturally occurring" materials, not materials present in a food as a result of "human activity."

"No Significant Risk" for Cadmium Under Proposition 65

The American Environmental Safety Institute has been working closely with the lead agency on the interpretation of Proposition 65, California's Office of Environmental Health Hazard Assessment ("OEHHA"), during its current consideration of an appropriate maximum allowable dose level ("MADL") for cadmium as a developmental toxicant by the route of ingestion. The Institute believes that when OEHHA completes its review, the level of 0.232 micrograms per day will be sustained, for it is clearly the proper scientific standard applicable under Proposition 65.

Oral Exposure Limit for Cadmium Should Be 0.232 Ug/Day

The most appropriate Proposition 65 "no observable effect" level for cadmium (below which no warning is required before an exposure occurs) is 0.232 micrograms per day ("ug/day"). The Institute derives this number by application of the most appropriate risk assessment for cadmium under Proposition 65's implementing regulation, *i.e.*, Title 22 of the California Code of Regulations, section 12803 for reproductive toxicity risk ("Reproductive Toxicity Risk Regulation"). The following brief review explains the Institute's analysis in reaching this conclusion.

The Institute first took the most sensitive study identified in the authoritative U.S. Department of Health & Human Services' Agency for Toxic Substances and Disease Registry's ("ATSDR") latest statement of the scientific literature regarding cadmium's toxic effects, "Toxicological Profile for Cadmium, Update 1999," (July 1999) (hereinafter "ASTDR Cadmium Profile"),[61] which identifies the study by Baranski B. Stetkieuicz I, Sitarek K, et al. 1983. "Effects of oral, subchronic cadmium administration on fertility, prenatal and postnatal progeny development in rats." *Arch*

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product.

[61] "This profile reflects ATSDR's assessment of all relevant toxicologic testing and information that has been peer-reviewed. Staff of the Centers for Disease Control and Prevention and other Federal scientists have also reviewed the profile. In addition, this profile has been peer-reviewed by a non-governmental panel and was made available for public review." ATSDR Cadmium Profile, at p. *v*.

Toxicol 54:297-302 (hereinafter the "Baranski" study), as establishing the "lowest observable effect level" of cadmium by way of ingestion as 0.04 mg/kg/day.[62]

The Institute then, pursuant to the Reproductive Toxicity Risk Regulation, divided this "lowest observable effect level" by ten (10) to obtain the "no observable effect level" of 0.004 mg/kg/day required for analysis under Proposition 65. The Institute then multiplied this latter number by the regulatory standard of 58 kilograms for a "woman with conceptus" specified in Title 22, California Code of Regulations, section 12703(a)(8) (whose use is mandated by the Reproductive Toxicity Risk Regulation) to obtain 0.232 mg/kg/day. The Institute then took this "no observable effect level" and divided it by one thousand (1,000), as required by the Reproductive Toxicity Risk Regulation, to obtain the result of 0.232 ug/day, as required by the Reproductive Toxicity Risk Regulation.

As a result, the most appropriate Proposition 65 "safe harbor" level for oral cadmium exposure of 0.232 ug/day.

The Solution:

One must put Big Chocolate's products and their adverse health impact on children in perspective. In the same manner that leaded gasoline, soldered lead cans, lead paint chips, plastic mini-blinds, lead glazed ceramics, PVC cords and related products have been found to contribute to household lead and other toxic metal contamination in dust that is in turn consumed by children, so children's direct ingestion of Big Chocolate's heavily marketed chocolate snack products must be viewed as a clear and present source of lead and cadmium in a child's diet.

By comparison to these more traditional sources of childhood lead poisoning, ingestion of lead in Big Chocolate's finished chocolate products can be seen to trigger not just Proposition 65 but also The Childhood Lead Poisoning Prevention Act of 1991 (California Health & Safety Code § 105275 *et seq.*) Indeed, with the California Department of Health Services estimating that more than 239,000 children (7.84% of all children in California) suffer from elevated blood lead levels, chocolate products should and must be labeled a source of "environmental lead contamination" under that statute. *See* 22 California Code of Regulations ("CCR") § 33008.

And clearly the U.S. Food and Drug Administration should amend its standards of identity for cacao (cocoa) products, which are set forth in 21 Code of Federal Regulations ("CFR") Part 163 to add a limit on the lead and cadmium present in cocoa products (there is none now), preferably to no more than 0.02 parts-per-million.

In light of these facts and the application of these relevant legal standards, the American Environmental Safety Institute believes that Big Chocolate can and thus must lower their lead and cadmium levels to mitigate this unnecessary and dangerous level of consumption of poisonous lead and cadmium by children in chocolate products.

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[62] "The most sensitive indicator of developmental toxicity appears to be impaired neurological development. This observation is supported by later studies that noted brain weights of mice dosed orally with cadmium had significantly decreased brain weights, with high levels of cadmium deposits in the brain (Kostial et al 1993; Zu et al. 1993b). The lowest exposures shown to cause these effects is animals are 0.02 mg/kg/m^3, 5 hours a day, 5 days a week, by inhalation (Baranski 1985) and 0.04 mg/kg/day, 5 days a week orally (Baranski et al. 1983). *Id.*, at p. 178.

CONCLUSION

"They can, so they should" is the standard that the American Environmental Safety Institute believes must apply to Big Chocolate and other purveyors of consumer products, not only as a proper legal standard, but also as the appropriate 21st Century preventive health care/moral standard. Corporate purveyors of popular products have a duty at a minimum to eliminate as much as possible the presence of dangerous levels of toxic poisons like lead and cadmium. To say such a chemical is simply present as a "natural" poison is not enough; with children's health hanging in the balance. The Institute believes that Big Chocolate can do at least as well as Big Oil, and get the lead out of chocolate just as lead was removed from gasoline.

Or at least Big Chocolate should behave at the minimal standards applied to Big Tobacco, and warn parents and their children about the peril of poisoning from the lead and cadmium in M&Ms and other chocolate products.

Thank you for your interest in this Petition. For further information on the Institute's petition, please contact either Roger Carrick or Art Angel at the Carrick Law Group, P.C., as follows:

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September 28, 2001

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RE: Proposition 65 Notices Concerning Hershey and Mars Chocolate

Dear Mr. Carrick and Ms. Corash:

In May of this year, we received sixty-day notices under Proposition 65 from the American Environmental Safety Institute, alleging that certain chocolate products made by Hershey Foods Corporation and Mars, Incorporated, require warnings under Proposition 65 due to the presence of lead and cadmium. Because these products are consumed by millions of Californians, we determined that the matter should be investigated especially carefully. Our investigative efforts have included our own research, consultation with independent experts, analytical testing of numerous products, and the review of substantial information provided by the representatives of both the noticing party and the alleged violators.

As you know, Proposition 65 does not apply to low levels of chemicals in foods that are deemed "naturally occurring" within the meaning of California Code of Regulations, Title 22, section 12501. Under this regulation, the company providing a food product is not responsible for "naturally occurring chemicals" in food if certain criteria are met. This regulation was designed to avoid ubiquitous warnings on many foods due to the existence of small quantities of some chemicals in the air, ground, and water, which results in their being present in food. The validity of the regulation was upheld in *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652. To fall within the terms of this regulation, however, the chemical cannot be present in the food as the result of any "known human activity," and it must be reduced to the "lowest level currently feasible" through processing, handling, or other techniques.

Based the information obtained in this investigation, we have concluded that the lead present in the products is not present due to known human activity, as that term is used in section 12501. In considering whether lead is present at the "lowest level currently feasible" within the meaning of section 12501, we note the recent lead levels proposed by the Committee on Cocoa Products and Chocolate of the Codex Alimentarius Commission of the World Health Organization. That committee proposed a standard of 1 ppm for cocoa power, 1 ppm for chocolate liquor and 0.1 ppm for cocoa butter. Although that standard was not adopted by the full Codex Commission, we believe that products meeting those strict levels qualify as being within the "lowest level currently feasible" under the regulation. Accordingly, based on the information we have obtained, lead levels falling under those levels would qualify as "naturally occurring" under the regulation.

In addition, the notices we received alleged that the products required warnings based on the presence of cadmium. While cadmium is a listed carcinogen, regulations specifically provide that it poses no significant risk of cancer where the exposure is through ingestion. (22 CCR § 12707(b)(3).) Cadmium also is a listed reproductive toxicant, and the Office of Environmental Health Hazard Assessment has proposed a regulatory safe-harbor level, i.e., the level deemed to be 1-1,000th of the No Observable Effect Level (for reproductive toxicity), of 4.1 micrograms per day. (See June 8, 2001 Notice of Proposed Rulemaking.) Based on the information we have obtained, the products in question fall well below this level, even before determining whether the chemical is "naturally occurring."

It is unusual for the Attorney General to publicly state that he has reviewed a matter under Proposition 65 and determined that it is not appropriate to proceed on the claim. We expect such public statements to continue to be extremely rare. Nonetheless, because these products are consumed by so many Californians, we think it is important for the public to be aware that the Attorney General's decision not to commence a civil action in this matter is based on a conclusion that the action would lack merit, after thorough consideration by this office.

Sincerely,

EDWARD G. WEIL
Deputy Attorney General

For BILL LOCKYER
Attorney General