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November 10, 2015

*Via Email to [monet.vela@oehha.ca.gov](mailto:monet.vela@oehha.ca.gov)*

Monet Vela  
Regulations Coordinator  
Office of Environmental Health Hazard Assessment  
1001 I Street  
Sacramento, CA 95812

**Re: Response to Request for Public Comment on OEHHA's Pre-Regulatory Proposal to Amend Proposition 65 Regulations for Naturally Occurring Chemicals in Foods**

To Whom It May Concern:

We write on behalf of the National Confectioners Association (NCA) and its members with respect to the California Office of Environmental Health Hazard Assessment's (OEHHA's) "Pre-Regulatory Proposal" to Amend Title 27 of the California Code of Regulations Section 25501. In addition to these comments, NCA endorses the comments being submitted on this proposal by the California Chamber of Commerce Coalition.

**Background.** NCA is the not-for-profit trade association of the confectionery industry. NCA represents more than 250 companies that manufacture chocolate, confectionery, gum and mints in the United States and another 250 companies that supply those manufacturers. A number of NCA's members also process raw cocoa beans into cocoa and chocolate. The majority of our members are small and medium-sized companies. The Association is committed to supporting science-based evidence and developing educational resources that reinforce the role of confections as a treat in a happy, balanced lifestyle.

Nearly 200 confectionery manufacturers are based in and/or have significant facilities and operations in California. Notable California confectionery companies include Nestle USA, Jelly Belly, Gimbals, Guittard, Ghirardelli, See's, American Licorice and many more. Confectionery companies employ approximately 7,000 people in the State California (per 2012 census data) with annual shipments valued at least \$1.73 billion. California consumers have and continue to enjoy a wide variety of NCA members' confectionery products, all of which comply fully with U.S. Food and Drug Administration and California food safety

requirements and guidelines, including those which address naturally occurring minerals like lead and cadmium.

Both of these minerals appear on the periodic table of the earth's elements, are not chemically synthesized by man, and may not be intentionally added to food. The good manufacturing practices (GMPs) and HACCP programs which are required of and implemented by NCA member companies assure that the levels of these minerals and of contaminants unintentionally present in their products do not pose health risks to consumers and have been reduced to the lowest level currently feasible.

Although the naturally occurring exception was intended to preclude Proposition 65 law suits against growers, preparers and sellers of foods containing naturally occurring substances, the current regulation is so ambiguously written that it has become virtually meaningless. Under a statutory scheme which imposes the burden of proof on defendants, as is true of Proposition 65, an exception which cannot be understood by enforcers and those whose products are covered as written, is no exception at all. As a result, the public health benefits of the exception, the drafters intended the exception to secure are lost. Instead of protecting and encouraging greater production and consumption of these natural foods, the absence of a meaningful exception once again encourages unnecessary litigation. Unlike synthetic foods whose constituents are the choice of the producer, natural constituents of foods are the results of forces not controlled by man. Without an exception on which growers, producers and sellers can rely, Proposition 65 tilts the table in favor of non-natural foods by exposing the natural foods to a growing wave of private enforcement claims.

Producers of confections containing naturally occurring minerals have faced repetitive Proposition 65 claims. First, virtually all major chocolate manufacturers were the subject of claims on lead and cadmium brought pursuant to the statute in 2001-2003 by a private prosecutor. The California Attorney General's office conducted its own thorough investigation of the plaintiff's allegations at the 60-day notice stage and concluded, in a published letter, that lead in (unsweetened) cocoa powder and chocolate liquor at levels under 1 ppm and under 0.1 ppm in cocoa butter were naturally occurring and reduced to the lowest level currently feasible.<sup>1</sup> Consequently, the letter concluded that the plaintiff's claims lacked merit. Nevertheless, the chocolate maker defendants were forced to spend millions of

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<sup>1</sup> September 28, 2001 Letter from Deputy Attorney General Ed Weil, attached as Exhibit A to these comments. Given how cocoa beans are grown and processed, the Attorney General would inevitably have concluded that levels of cadmium found in chocolate products were also naturally occurring and reduced to the lowest level currently feasible; however, as the letter makes clear, the Attorney General found it unnecessary to reach that issue because the cadmium levels were already under the 4.1 microgram/day safe harbor level.

dollars and endure years of discovery and a barrage of adverse publicity generated by the plaintiff so as to get the claims dismissed.<sup>2</sup>

Some years later, several makers of some imported Mexican-style candies which contained naturally occurring lead again found themselves named in Proposition 65 litigation.<sup>3</sup> As a result, a clear standard of < 0.100 ppm for lead in candy frequently consumed by children was adopted by the State and FDA, with the active support of NCA. The California Attorney General and the Los Angeles Superior Court recognized the same lead standard for candy as the exempted naturally occurring level under Proposition 65.<sup>4</sup>

Over the past two years, NCA members and their customers have been subjected to yet another round of Proposition 65 bounty hunter litigation – this time concerning lead in licorice products. The levels of lead in these products were already below the State's and FDA's prior guidelines for lead in chocolate and other types of candy. But, to avoid costs of litigation, manufacturers of these products had no choice but to pay the plaintiff and agree to reformulate their products. Contrary to the intent of the regulation, they did so by eliminating some natural ingredients and replacing them with artificial flavoring so as to reduce lead content by a few parts per billion.

**Current Outlook.** Notwithstanding the above and the industry's consistent record of producing safe products and of compliance with Proposition 65, makers of confectionary products are now facing yet another wave of threatened Proposition 65 claims and lawsuits concerning lead and cadmium in chocolate products. These serial claims, arise in part as the result of private plaintiffs' refusal to acknowledge that any significant portion of lead or cadmium in cocoa-based products is properly excluded under Section 25501 of Proposition 65's regulations.

**General Comment.** OEHHA should proceed to revise Proposition 65's existing naturally occurring chemicals regulation to make its application more straightforward so that all affected parties can understand, without the need for litigation, when foods are entitled to an

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<sup>2</sup> Evidence in the case revealed that the average levels of naturally occurring lead and cadmium in finished chocolate products varied as did levels of other nutrients and that they were a function of the proportion of cocoa bean-derived ingredient (i.e., cocoa powder, chocolate liquor, cocoa butter) found in them, such that higher naturally occurring lead and cadmium levels were found in unsweetened cocoa powder and dark chocolate products while the addition of milk and other non-cacao based ingredients in candy recipes resulted in lower lead and cadmium concentrations in other types of chocolate products. Exhibit B to these comments presents the more detailed evidence from the case.

<sup>3</sup> The claims arose when some other, clearly adulterated, Mexican candies were embargoed at the border and became the subject of media attention.

<sup>4</sup> *People et al. v. Alpro Alimento Proteinicos, et al.*, Los Angeles Superior Court No. BC 318207, consent judgment approved and entered on August 3, 2006.

exemption on this basis. To fulfill its original intent, the regulation's structure needs to be revised so that its application to minerals and other natural constituents seen in unadulterated foods becomes fairly routine, not a rare, seldom seen, exception. In short, a far more comprehensive and meaningful approach to revision of this regulation is needed than OEHHA has currently proposed.

*Specific Comments.*

***OEHHA Should Include in Its Rule Section 25501 Allowances for Cocoa-Bean Derived Ingredients (and/or for Finished Chocolate Products and Licorice).*** NCA appreciates OEHHA's willingness to promulgate levels of naturally occurring minerals in specific types of foods that will be deemed to be naturally occurring for purposes of Section 25501 of the Proposition 65 regulations, including ingredients, such as rice and milk, used by confectionary companies. However, these allowances are too narrow in scope and, within their scope, may be set too stringently – see comments of the California Chamber of Commerce Coalition in this regard, which NCA supports.

The prior history of Proposition 65 cases concerning lead and cadmium in chocolate products and cocoa-based ingredients, the prior Attorney General and court findings associated with them, and Governor Brown's call for reforms to reduce vexatious Proposition 65 litigation, all provide compelling grounds for OEHHA to specify additional Section 25501 allowances for them within this rulemaking. The fact that cocoa beans are not cultivated in California is immaterial as, among other things, the feeding roots of cocoa trees are found at depths below areas where soils may be influenced by anthropogenic activities and the trees are typically grown in remote rainforest environments in mountainous areas characterized by volcanically-influenced soils lying far from paved roadways and urbanization.

NCA recommends that OEHHA adopt the previously-approved levels of < 1 ppm for lead in unsweetened cocoa powder and chocolate liquor and <0.1 ppm for lead in cocoa butter as Section 25501 exemptions.<sup>5</sup> As the factual issues concerning whether they are naturally

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<sup>5</sup> On October 20, 2015, the Attorney General's office issued a further letter concerning lead in chocolate products indicating that the conclusions reached in its prior September 28, 2001 letter were based on the information available to it at that time; that unspecified additional studies have since become available but have not been evaluated relative to whether or not the levels of naturally occurring lead identified in the 2001 letter remain appropriate; and emphasizing that the 2001 letter was not a regulation with binding effect for adjudicative purposes. While it is obviously designed to effect neutrality in the event of future litigation, the Attorney General's new letter is not an impediment to OEHHA's potential adoption of Section 25501 allowances for cocoa-based products, the stated goal of which is to reduce the prospect of litigation over naturally occurring issues in the first instance. It is also important to recognize that the Attorney General's new letter does *not* take the position that the naturally occurring levels identified in their 2001 letter are necessarily inaccurate or invalid or, for that matter, that lead in cocoa-based products and chocolate currently available for sale in California is *not* naturally occurring and reduced to the lowest level currently feasible. Indeed, in resolving recent Proposition 65 litigation involving cocoa-based ingredients, courts have already embraced and

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occurring are identical, the same or higher levels could be authorized for naturally occurring cadmium in these ingredients as well.

There are also sufficient grounds for OEHHA to promulgate Section 25501 allowances for lead in finished chocolate products and licorice (when made with natural ingredients like molasses). In this regard, NCA recommends the 0.100 ppm lead standard that was previously approved as the naturally occurring level for Proposition 65 purposes and which also serves as the State's and FDA's lead in children's candy guideline.

***Naturally Occurring Allowances Promulgated by OEHHA Must be Comprehensive as to Section 25501(a) in its entirety.*** It is insufficient for OEHHA to tie the naturally occurring allowances it promulgates to subsection 25501(a)(2) of the existing regulations only, at least insofar as allowances for cocoa-based ingredients and finished chocolate products and molasses-derived licorice are concerned. To have any meaningful utility in adding certainty and reducing litigation, it is insufficient to have allowances address only the “naturally occurring” and not the “lowest level currently feasible” portion of the regulation. The aforementioned prior Attorney General and court findings concerning the naturally occurring lead levels in cocoa/chocolate and candy are expressly inclusive of the latter, as they must be for this provision to serve its purpose and provide a meaningful exception. Addressing only half the equation will not fundamentally improve the current situation. Lawsuits about natural foods and food ingredients will continue, and companies which cannot afford to litigate “reduced to the lowest level currently feasible” – which constitute the overwhelming majority of growers, producers, servers, and sellers of these products – will be forced to settle even claims which have no merit.

We very much appreciate the opportunity to offer our views and comments on this issue and look forward to OEHHA amending its proposal accordingly and/or working with us further to that end.

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given binding effect to allowances based on the 2001 letter's levels. *See e.g.*, consent judgment approved in *Environmental Research Center v. Clif Bar & Co., et al.*, San Francisco Superior Court No. CGC-13-532935.

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Sincerely yours,

A handwritten signature in black ink, reading "Alison Boder". The signature is written in a cursive style with a large, looping initial "A".

Alison Boder  
Executive Vice President  
National Confectioners Association

cc: Matthew Rodriguez, Secretary, CalEPA  
Dana Williamson, Cabinet Secretary, Office of Governor Jerry Brown  
The Honorable Luis Alejo, Chair, Assembly ESTM Committee  
The Honorable Bob Wiekowski, Chair, Senate Environmental Quality Committee

**EXHIBIT A**

**BILL LOCKYER**  
Attorney General

State of California  
**DEPARTMENT OF JUSTICE**



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September 28, 2001

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Michele Corash  
Morrison & Foerster  
425 Market Street  
San Francisco, CA 94105-2482

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.

Roger Lane Carrick  
September 28, 2001  
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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 powder, 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 1-1,000<sup>th</sup> 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,

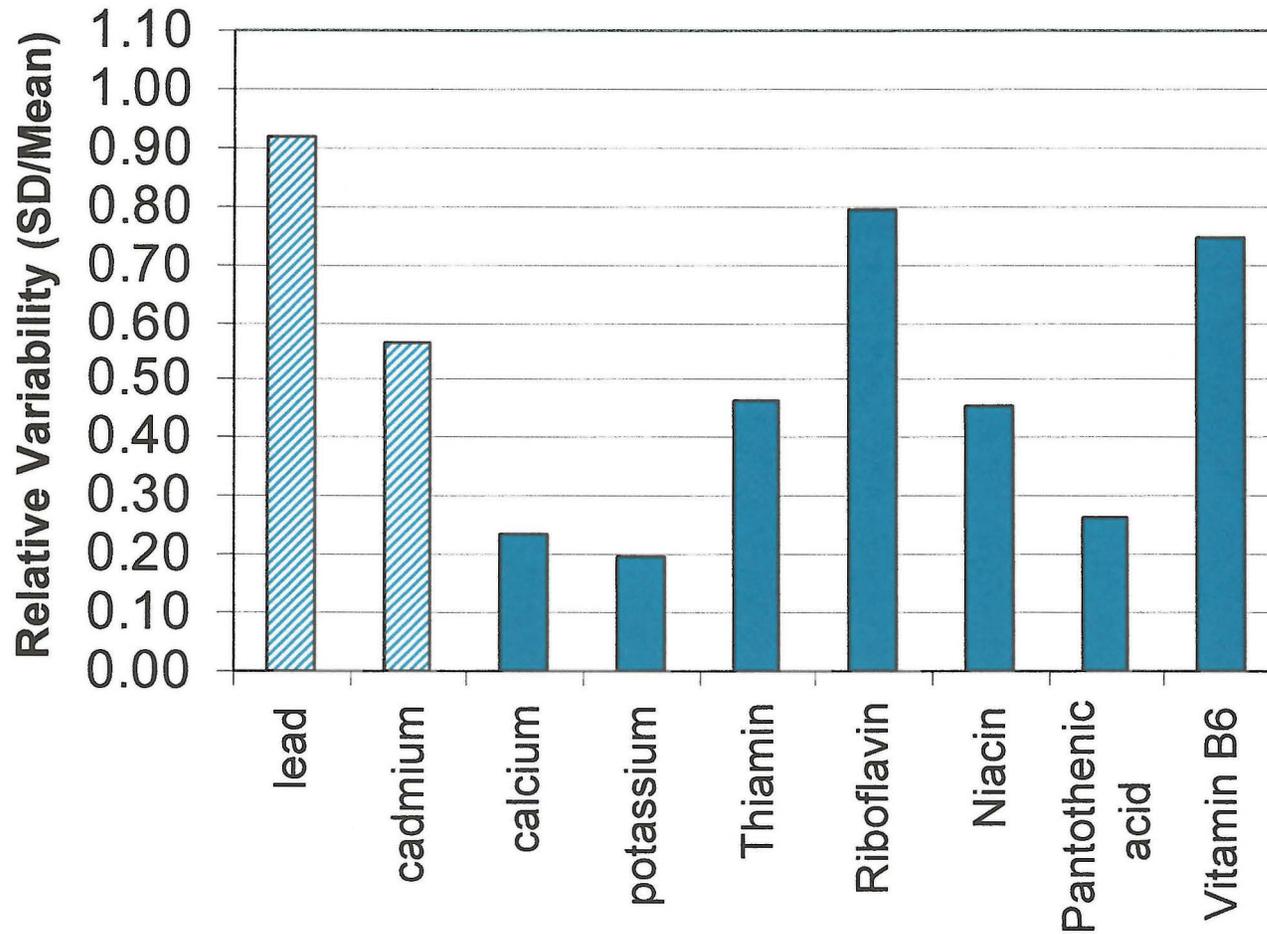


EDWARD G. WEIL  
Deputy Attorney General

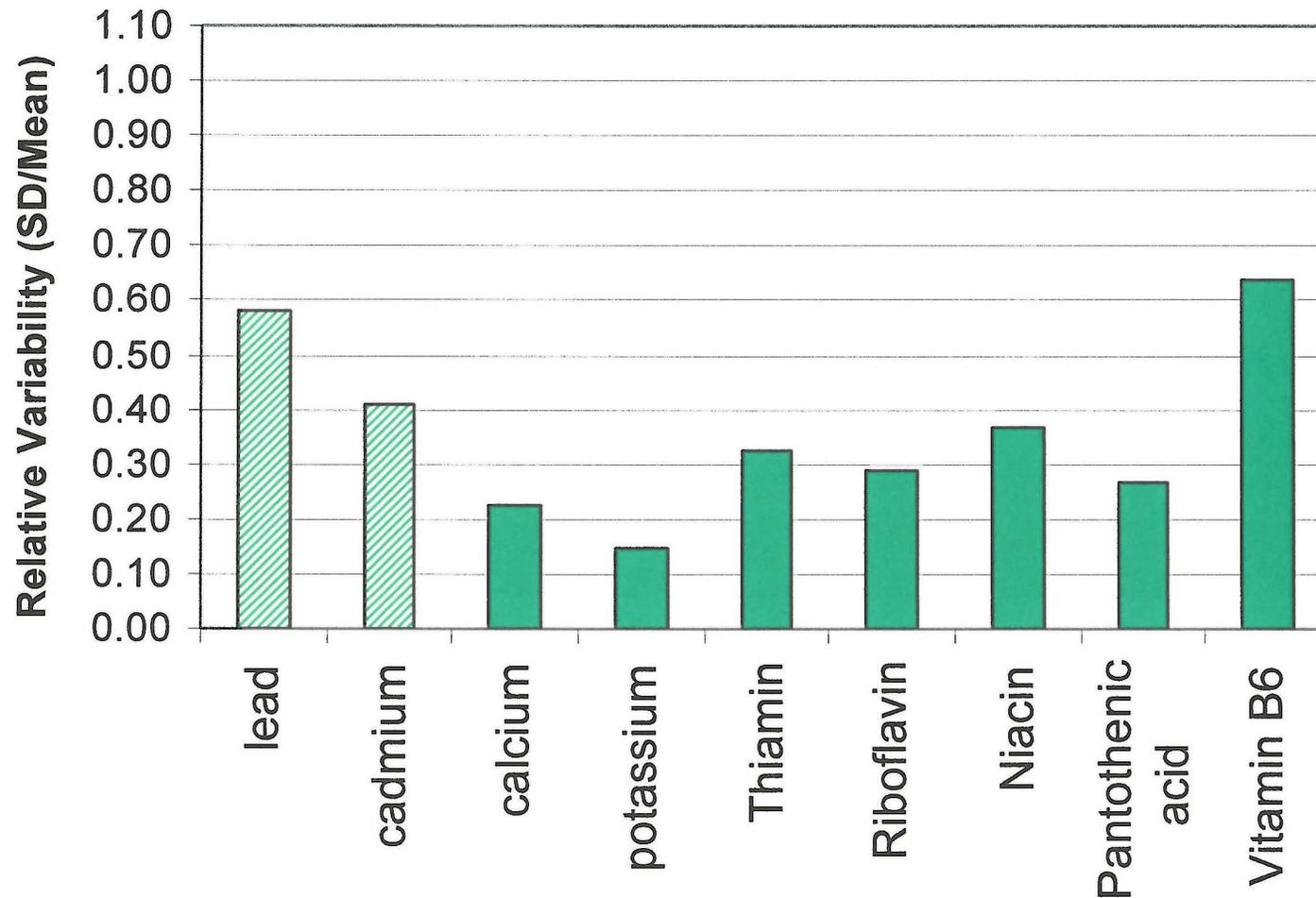
For BILL LOCKYER  
Attorney General

## **EXHIBIT B**

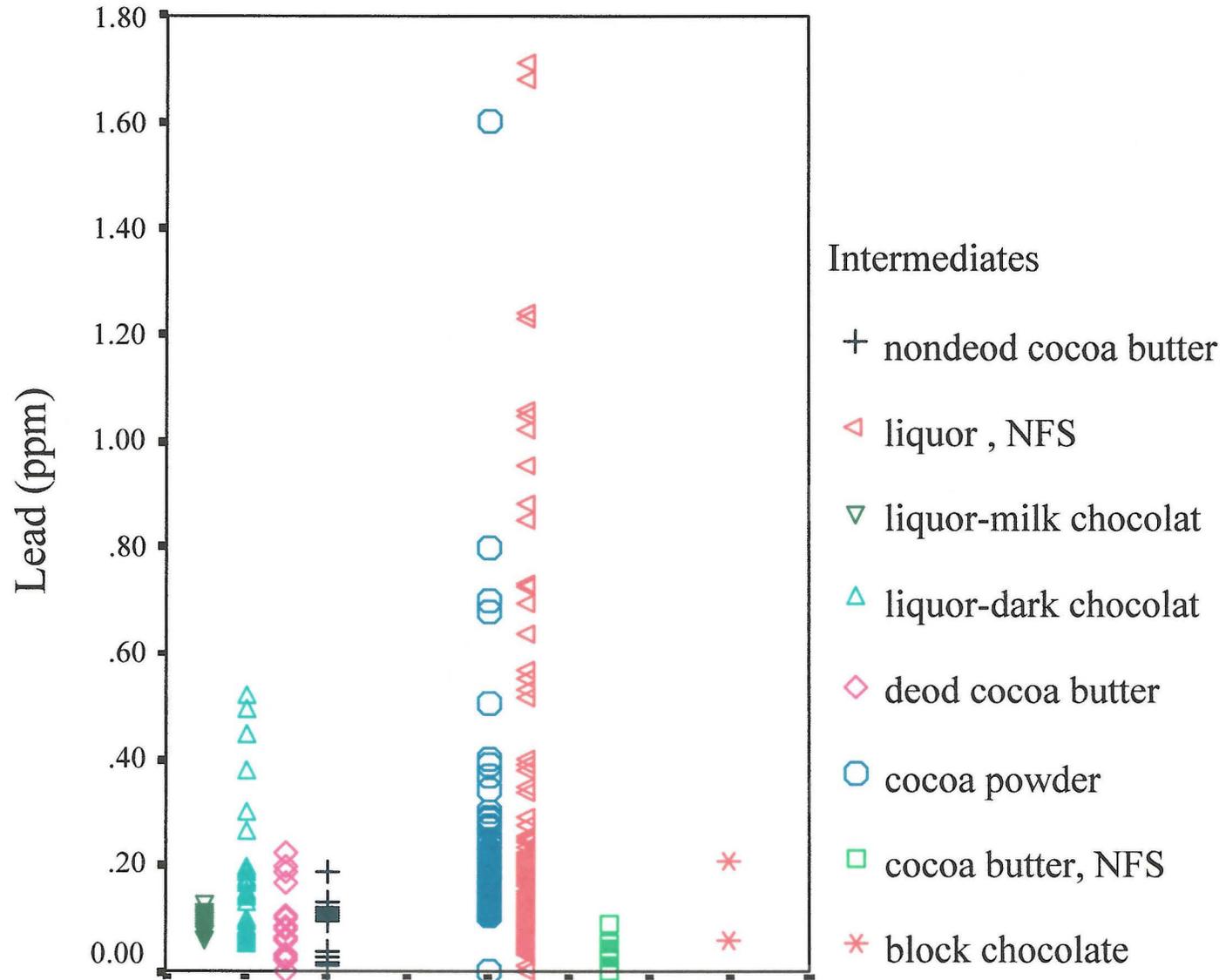
# Comparison of the variability of lead, cadmium, and nutrient levels in dark chocolate (unsweetened)



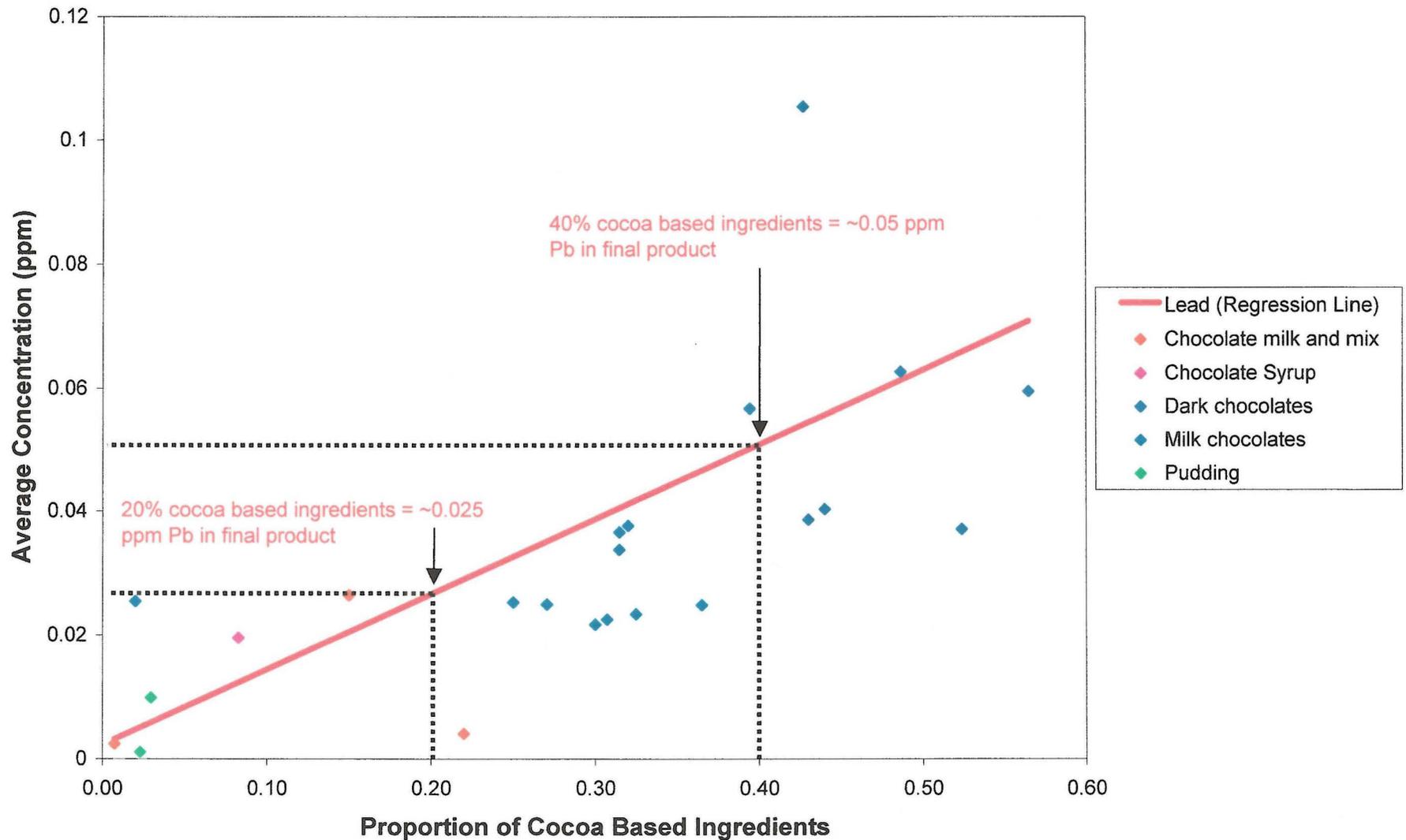
# Comparison of the variability of lead, cadmium, and nutrient levels in milk chocolate products



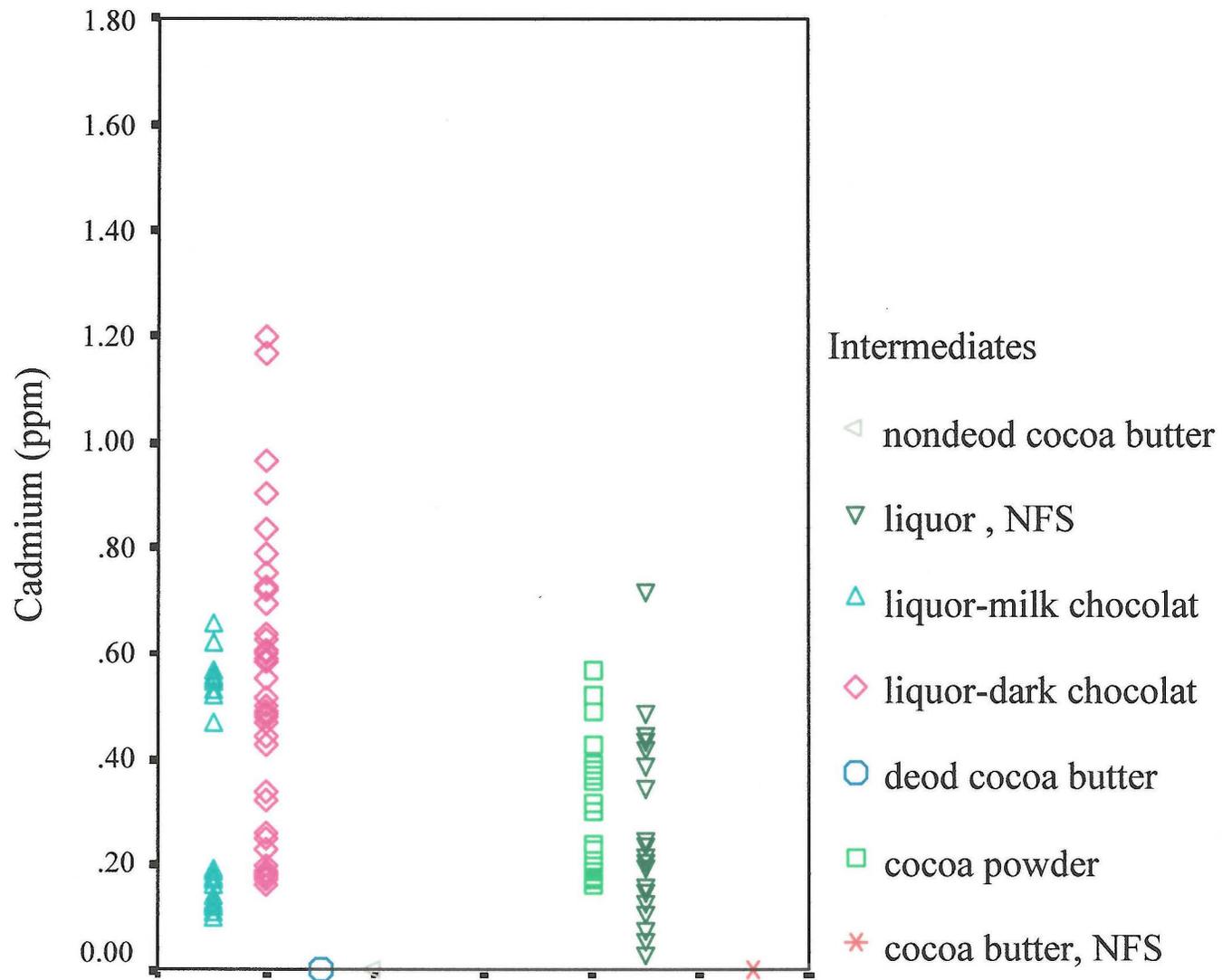
# Lead Concentrations in Cocoa-based Intermediates



# Average concentration of lead in chocolate products increases as proportion of cocoa-based ingredients increases



# Cadmium Concentrations in Cocoa-based Intermediates



# Average concentration of cadmium in chocolate products increases as proportion of cocoa-based ingredients increases

