

The State of Prop 65 Compliance in 2019

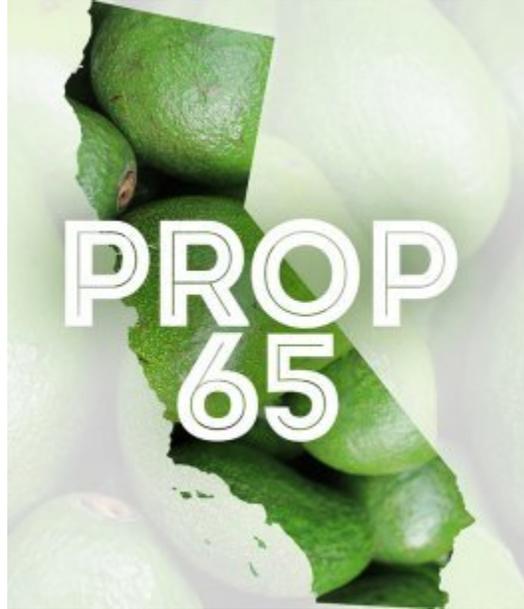


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OEHHA Takes Steps to Finalize Proposed Coffee Regulation

By Jack Schatz | The State of Prop 65 Compliance in 2019

California's Office of Environmental Health Hazard Assessment (OEHHA) has taken a potentially final step toward exempting coffee from Proposition 65 warnings.

The agency had proposed in June 2018 that it intended to create a specific exemption for exposures to acrylamide and other Proposition 65-listed chemicals that are present in coffee as a result of roasting coffee beans

The regulation would establish as a matter of law that exposures to acrylamide and 14 other Proposition 65 chemicals, created when coffee beans are roasted, pose no significant risk of cancer, thereby exempting them from warnings:

- **25704. Exposures to Listed Chemicals in Coffee Posing No Significant Risk**

Exposures to listed chemicals in coffee created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer.

Public comments on the proposal closed on August 30, 2018. OEHHA has now completed its review and response to comments, including multiple submissions from the Council for Education and Research on Toxics (CERT), a Proposition 65 plaintiff.

CERT is currently locked in a Proposition 65 enforcement battle with over 60 companies that roast, distribute, or sell coffee at retail, seeking civil penalties and Proposition 65 warnings about acrylamide in coffee. CERT also brought a separate action against OEHHA, challenging the legal and scientific validity of the proposed exemption. Both cases are currently pending in Los Angeles Superior Court.

OEHHA has now completed its review and response to public comments. On January 10, 2019, OEHHA submitted the regulation — with no change to the proposed language — along with its 160-page final statement of reasons to the Office of Administrative Law (OAL) for review.

OAL has until February 19, 2019 to approve the regulation, reject it, or request further information from OEHHA.



LA Superior Judge Elihu Berle ruled that coffee sold in California must carry a Prop 65 warning

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Skin-Lightening Creams Sold by Amazon.com Contain Dangerous Mercury Levels, NGO Claims

By Jack Schatz | The State of Prop 65 Compliance in 2019

As You Sow, a non-profit foundation has issued a notice of violation to sue Amazon.com for failing to comply with the Proposition 65 requirements that would require the company to warn consumers about certain skin-lightening creams that the non-profit contends contain mercury at dangerously high levels. Proposition 65 is the California's Safe Drinking Water and Toxic Enforcement Act.

According to the notice letter that was sent on Nov. 21, to the biggest online retailer in America, the company failed to provide the legally-required warning to consumers of the skin-lightening creams sold on Amazon.com that contain dangerously high levels of mercury. Some creams purchased and tested by the Mercury Policy Project showed mercury content at up to 38,000 times the legal limit set by the U.S. Food and Drug Administration (FDA). As You Sow claims that although Amazon.com had been previously notified of their harmful and illegal content, the company continues to provide the creams available for sale on its website, As You Sow alleges.

The FDA limit for mercury on skin creams has been only one part per million (ppm) since 1973, but Amazon.com continues to list skin-lightening creams that contain a much higher amount of the substance. As You Sow's CEO Andrew Behar claims. Behar said that Amazon's cavalier approach, when informed of the high mercury content in the whitening creams on its website is "particularly worrisome." He added that the foundation is taking legal action to at least force Amazon to comply with the legal mandate to warn the consumers that the whitening creams contain mercury. The FDA classifies creams with high levels of mercury as adulterated drugs.

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Mercury is a highly neuro-toxic metal that affects the renal, reproductive and central nervous systems. It can cause poor muscle tone in children, tingling or numbness around the lips, in the feet or hands, anxiety, hypertension and memory loss among other health problems.

Mercury is a very dangerous poison because the health risks from it are not limited to the users of skin products containing the toxic metal. Mercury vapors can contaminate the air and cause harm to other people as well as pets.

California's [Department of Public Health \(DPH\)](#) warned the public in 2012 about high mercury levels found in unlabeled skin lightening cream allegedly smuggled from Mexico. The problem was discovered when a 39-year-old Mexican-American woman in Alameda County was hospitalized due to depression, headaches, numbness and forgetfulness which are some of the symptoms of mercury poisoning. Medical officials searched the patient's home to determine how she was poisoned and they found the lightening cream.

“Mercury is easily absorbed through the skin. just touching it exposes one to the dangers of mercury poisoning. For example, if someone in a household or workplace is using the whitening cream with mercury, other people can absorb the substance from the user’s laundry, personal items, and other surfaces that he or she has come in contact with. Nursing mothers using the cream can expose their newborns through breast milk.”

According to Gordon Vrdoljak, of the California Department of Public Health, notes that regular users of creams with mercury can spread the toxic element with their hands to the food they handle, on the countertops and gadgets they use or on the clothes their kids wear.

Although Amazon knows about the dangerous content of the creams identified by As You Saw, it still sells the product and did not want to provide the required notice or warning to its consumers. Amazon’s reason for its refusal to warn its consumers of the skin-whitening products is that the warning “will simply upset Amazon’s customers” and cause negative publicity for the company.

A staff attorney at As You Sow, Sylvia Wu said that California’s Prop 65 has labeling requirements to provide consumers with crucial information about a product.

Other states’ departments of public health have also issued warnings about the dangers of mercury poisoning and have advised consumers to:

- Read the label of cosmetics and personal care products. Avoid any product that lists mercury as one of the ingredients. Buyers should be aware of the following synonyms for mercury: mercurio, calomel, mercuric and mercuric chloride.
- Avoid products that do not specify the ingredients on the label which are required by federal



- law.
- The Department of Public Health warns consumer to be careful in buying imported anti-aging and skin whitening products especially Mexican made.

This is not Amazon. com’s first violation of FDA standards through its illegal sale of harmful cosmetics to American buyers. However, the federal agency has not acted to stop the problem, leaving consumers to protect themselves.

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OEHHA Adds Two chemicals to Prop 65 list, Proposes to Add PCBTF

By Jack Schatz | The State of Prop 65 Compliance in 2019

California's Office of Environmental Health Hazard Assessment (OEHHA) has added N-nitrosohexamethyleneimine and gentian violet to its list of carcinogens under Proposition 65 and issued its notice of intent to also add para-chlorobenzotrifluoride (PCBTF), a solvent to the Proposition 65 list of carcinogens.

Companies using any of approximately 900 substances listed under Prop 65 are required to provide warnings to Californians that using their products may possibly expose them to the chemicals identified as carcinogens or toxic to the reproductive system.

Gentian violet or crystal violet is a dye and an antifungal while N-nitrosohexamethyleneimine is used as an industrial intermediate in chemical production and as an ejector seat explosive in military jet fighter planes. The two chemicals were added to Prop 65 list after an advisory group of 'state's qualified expert' confirmed during a California Carcinogen Identification Committee (CIC) [meeting](#) that the substances met the criteria to be considered carcinogenic. The two substances were listed effective November 23.

In its notice of intent, the OEHHA announced that it's taking the steps to list PCBTF based on the 'authoritative bodies' mechanism after a 2018 National Toxicology Program (NTP) reported "clear evidence" of PCBTF's carcinogenicity.

The NTP's report on PCBTF's carcinogenicity was titled "*Toxicology and Carcinogenesis Studies of p-Chloro- α,α,α -Trifluorotoluene in Sprague Dawley Rats.*" The reported findings met the sufficiency of the evidence and formal identification criteria needed to be added to the Prop 65 list. PCBTF is also used as a solvent in inks, coatings and paints.

The use of PCBTF is important for manufacturers in California because its contribution to ground-level ozone formation is insignificant which makes PCBTF an approved alternative solvent that meets the strict requirements for volatile organic compound (VOC) emissions.

The public comments period on the PCBTF proposal was initially set to end on December 24, but the American Coatings Association (ACA) requested an extension. California's Office of Environmental Health Hazard Assessment (OEHHA) agreed to extend the public comment period until January 23, 2019.



Walgreens Implements Worldwide Chemicals Policy

By Jack Schatz | The State of Prop 65 Compliance in 2019



The global pharmacy giant Walgreens Boots Alliance, which has over 18,500 stores, has finally implemented its long-awaited chemicals policy that the company announced in 2014.

Walgreens's chemicals policy took effect on November 8. The new policy includes a restricted substances list (RSL). The RSL includes toluene, triclosan, plastic microbeads, xylene and chemical groups such as parabens, phthalates, NP ethoxylates and nonylphenol,

The RSL will be implemented on personal care, household cleaning and baby products in Walgreens as well as on Boots UK-owned consumer retail lines and brands. Walgreens Boots Alliance was formed when Walgreens completed its 100% purchase of Alliance Boots UK in 2014 from just 45% in 2012.

According to the company's website, it has started coordinating with its suppliers for the reformulation of the applicable products such that they are free of the listed substances not later than 2021.

To move the reformulation forward, Walgreens is encouraging suppliers to choose ingredients based on the criteria of U.S. EPA's Safer Choice Initiative. It also advises suppliers to find and assess safer alternatives at ChemSec's Marketplace, an online portal that features safer substitutes to hazardous substances.

Every year, Walgreens plans to report its progress as well as update its RSL as "more scientific information becomes available". The content on the RSL is based on various authoritative lists.

Aside from its RSL, the company has made a list of chemicals that it will monitor and try to restrict and/or phase out from its product portfolio. Eventually, this list's chemicals which are not publicly available will be added to the RSL of the company.

Personal care products

Walgreens will keep an eye on these six authoritative lists particularly for personal care and beauty products:

- California's Proposition 65 - reproductive and developmental toxicants and carcinogens;
- The International Agency for Research on Cancer (Iarc) - categories 1, 2A and 2B
- EPA's Toxics Release Inventory PBTs (Persistent, bioaccumulative and toxic substances);
- EU - Cosmetics Regulation Annex II;

- EU REACH – Annex XVII CMRs (Appendices 1-6); and
- EU – Priority Endocrine Disruptors (Categories 1, 2);

These six lists are under the Beauty and Personal Care (BPC) stewardship list. The BPC list was developed from a collaboration of The Sustainability Consortium, the UK organisation Forum for the Future together with Wal-Mart, Walgreens, Target and other companies in the industry.

Walgreens’ policy requires that all suppliers of its owned or third party brands keep tracking the use of the chemicals in their beauty and personal care products.

Transparency

To meet the increasing consumer demand for public disclosure of ingredients used, the company plans to:

- urge formulated products suppliers to publicly disclose digitally or on package labels the list of ingredients they have intentionally added;
- encourage suppliers to get US EPA’s Safer Choice, Cradle to Cradle and other credible certifications and
- ask suppliers post the ingredients on product labels of all own-brand household cleaners before the end of 2019.

The Mind the Store coalition of NGOs said Walgreens, Rite Aid and Amazon were recognized as the “most improved” retailers according to the latest chemicals management [report card](#). Walgreens got a B-, which ranked it in the first 10 out of 40 US retailers evaluated.

Mind the Store commented on its report card regarding Walgreens’ policy, saying that it could improve by strengthening accountability measures, conducting its own testing and requiring that suppliers test in approved third-party laboratories. The comment added that Walgreens should expand the extent of its policy outside the current categories covered. It should also require suppliers to conduct other assessments to prevent regrettable substitutions. Mind the Store also urges Walgreens to be a signatory to the [Chemical Footprint Project \(CFP\)](#). The CFP provides companies with a tool to benchmark their status as they choose safer alternatives to reduce and eventually eliminate their use of hazardous chemicals.

CALIFORNIA SUPREME Court De-Publishes Recent Appellate Opinion

By Jack Schatz | The State of Prop 65 Compliance in 2019



The California Supreme Court has declined to review a decision that federal law preempts state-mandated warnings about cancer risks associated with a chemical in cereals made by Post Foods LLC, General Mills Inc., and Kellogg USA Inc.

The High Court on Oct. 31 ordered the lower court's opinion to be de-published. The de-publication of the Appellate Opinion now only binds the parties in this case and cannot be cited as legal authority in future cases involving chemicals in other foods and beverages.

The Appellate Court Opinion found that Proposition 65 warnings concerning acrylamide were preempted by the FDA policy that encourages consumers to eat cereals containing whole grains for a healthy diet. Acrylamide is a chemical by product of baking and cooking starchy foods at high temperatures. The chemical was listed as a carcinogen in 1990 based on its use in industrial chemical applications. In 2002 Swedish scientists discovered the Maillard Reaction, which causes the formation of starchy foods in cooking.

California Agency Proposes New Interim Restrictions on Use of Toxic Pesticide Chlorpyrifos

By Jack Schatz | The State of Prop 65 Compliance in 2019

The California Department of Pesticide Regulation (DPR) has issued proposed interim restrictions on the use of the pesticide chlorpyrifos. The pesticide is implicated in a number of human illnesses including neurological harm to babies' brains. The new restrictions are meant to increase protection from potential exposure to the pesticide while the DPR determines a formal regulatory procedure to include chlorpyrifos in the list of toxic air contaminants as well as the permanent restrictions on its use.

DPR is recommending January 1, 2019, as their implementation date of the interim measures by the county agricultural commissioners.

DPR Director Brian Leahy said that for years the agency has been working with growers to find alternatives to chlorpyrifos. In the meantime, the interim measures are part of the agency's efforts to protect the environment and human health.

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The interim measures that cover the application method and the notice of intent include the following:

1. Some of the restrictions on the application method

- No aerial applications of chlorpyrifos. Applications must not be above 4 feet above ground and within the wind speed of 3 to 10 mph.
- The use of chlorpyrifos will be restricted to "critical uses" only. "Critical uses" means that the University of California Cooperative Extension has determined that there are few or no alternative pesticides.
- Pesticide applications require a buffer zone of a quarter-mile or 1320 feet. If the buffer zone extends into adjacent property, a written permission is required from the owner or operator of the property. The written permission should also specify that they will be out of the buffer during the required period during and after the pesticide application.
- Restrictions for airblast, chemigation and granular applications.



2. Notice of intent.

A notice of intent (NOI) must be submitted to the county agricultural commissioner (CAC) at least 24 hours before the application. The NOI should include the time of application, the map showing the area of application and the buffer zone, permission that the buffer zone can extend into other properties and other documents required.

The DPR has released a complete list of recommended restrictions on chlorpyrifos in products used as agricultural inputs.

The pesticide manufactured by Dow Chemical Co. which is used against pests in about 60 agricultural crops, including grapes, asparagus, almonds, alfalfa, cotton and oranges — has been strongly criticized by lawmakers, regulators and the courts. Gradually, growers began using safer alternatives. According to the DPR, in 2016, the use of chlorpyrifos has dropped by over 50 percent to 900,000+ pounds from two million pounds in 2005.

The DPR designated chlorpyrifos as a restricted material in California in 2015. A product containing a restricted material can only be used by licensed professionals who have been issued permits by the local county agricultural commissioner. Then, in 2017, chlorpyrifos was listed under Proposition 65 as a substance that can cause reproductive harm.

In September 2018, the DPR proposed that chlorpyrifos is designated as a toxic air contaminant after extensive scientific review and public comment. Under California law, an air pollutant is a substance that can increase cases of serious illness or death as well as a present or potential danger to human health. The 45-day period for public comments on the proposed designation ended on Nov. 9.

There have been various reports about illnesses caused by exposure to chlorpyrifos. In recent years, farmworkers in California became sick after exposure to the airborne pesticide.

Last year, over three dozen cabbage farmworkers in Kern County became sick from exposure to the pesticide that drifted from nearby farms. Some workers complained of nausea, vomiting and had to seek medical treatment.

This year, at least 13 people were affected, mostly workers in Solano County, where the pesticide was used in an almond orchard.

California's DPR recommends that county agriculture commissioners implement the newly- issued requirements in January when they issue permits for pesticide application. Another DPR recommendation is to limit the use of chlorpyrifos to certain crops and pests only.

The DPR is required to discuss with other state and local agencies the permanent regulatory measures needed after chlorpyrifos has been designated as a toxic air contaminant. The state and local agencies include the CACs, California Air Resources Board, the Office of Environmental Health Hazard Assessment and local air districts. Establishing the regulatory measures may need up to two years to complete.

OEHHA Considers the Future of Prop 65 Short-Form Warnings

By Jack Schatz | The State of Prop 65 Compliance in 2019

There could be future changes to the use of 'short-form' warnings as a way to comply with Prop 65 requirements. According to the delegates at the 6th Annual Regulatory Summit USA, California's Office of Environmental Health Hazard Assessment (OEHHA) may be reviewing if 'short-form' warnings can satisfactorily meet Proposition 65 requirements. The delegates added that there is "no guarantee" that "short-form warning" shall continue as a future compliance alternative in many cases.

The recent amendments to California's Prop 65 Warning Regulations law were one of the topics discussed in the session on US state-level actions. OEHHA had amended the rules on how manufacturers and retailers should provide 'clear and reasonable' warning to people if their products use any of the about 900 substances listed under California's Prop 65.

The new regulations were said to have "caused compliance confusion" among those who are supposed to implement them. The confusion was specifically regarding the requirement to identify the substance for which the warning is posted.

Many companies have been using the 'short-form' warning on products labels. In the "short-form warning, it is not required to include the name of the chemical for which a product warning is provided.

According to OEHHA, the "short-form" warning was intended for small products or, items where there is limited space for the label. However, there is no rule that prohibits its use on the product in bigger containers or packages.

DLA Piper partner George Gigounas informed conference attendees that the flexibility of using the "short-form" warning is being questioned. He said that businesses should be aware that there is no assurance that they can continue using the alternative form of warning because Oehha "appears to be examining the issue."

OEHHA spokesperson Sam Delson confirmed that the agency is indeed looking into the use of "short-form" warning but they "have not made any decisions." Delson added that any regulatory revisions shall be done based on the California Administrative Procedures Act which requires inputs and comments from the public.



Mr. Gigounas also told the delegates that should OEHHA have new rules on the use of “short-form” warning, he is confident that the changes would take effect “prospectively, not retroactively.” He added that businesses would be given time to study the new changes before they take effect.

OEHHA Proposes to List Cancer Drug Under the Formally Required to be Labeled and Identified Mechanism of Proposition 65

By Jack Schatz | The State of Prop 65 Compliance in 2019

The California Environmental Protection Agency’s Office of Environmental Health Hazard Assessment (OEHHA) announced that it intends to list bevacizumab as known to the state to cause reproductive toxicity (developmental and female endpoints) under the Safe Drinking Water and Toxic Enforcement Act of 1986, more commonly known as Proposition 65. OEHHA notes that this action is being proposed under the “Formally Required to Be Labeled or Identified” listing mechanism, which is most often used to list certain drugs approved by the U.S Food and Drug Administration that cover or contain chemical compounds under Proposition 65. Listings under the Formally Required to be labeled or Identified listing mechanism are rarely contested in any meaningful way.

For example, the proposed listing of Bevacizumab is a cancer treatment drug known by its brand name, Avastin. It is a treatment for many different types of cancers, such as colon cancer, non-small lung cancer and also in the treatment of ovarian cancer. It is also used in chemotherapy.

Chemical	CAS No.	Toxicological Endpoint	Reference
Bevacizumab	216974-75-3	Female reproductive toxicity Developmental toxicity	FDA (2018)

Carcinogen Identification Committee Lists Two New Carcinogens

By Jack Schatz | The State of Prop 65 Compliance in 2019

California's Office of Environmental Health Hazard Assessment (OEHHA) has added gentian violet (CAS No.548-62-9) and (N-nitroso-hexamethyleneimine (CAS No. 932-83-2) to the list of chemicals known to the state to cause cancer for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986, more commonly known as Proposition 65. At a public meeting held in Sacramento on November 1, 2018, the Carcinogen Identification Committee (CIC) in its official capacity as the "state's qualified experts" (SQE) determined that gentian violet and N-nitroso-hexamethyleneimine were clearly shown by scientifically valid testing according to generally accepted principles to cause cancer. Regulations for the listing of chemicals by the CIC are described in Title 27, California Code of Regulations, section 25305(a)(1). Both chemicals were listed unanimously by each of the CIC committee members. Both chemical listings took effect on November 23, 2018. Proposition 65 enforcement concerning both chemicals will commence on November 23, 2019.

following a one year period after the listing date of the listed chemicals.

Crystal violet or gentian violet is a triarylmethane dye used as a histological stain and in Gram's method of classifying bacteria. Crystal violet has antibacterial, antifungal, and anthelmintic properties and was formerly used as a topical antiseptic.

N-Nitrosohexamethyleneimine is a cyclic nitrosamine. It is used as an explosive in ejector seats in military jet fighter planes. Exposures to

N-nitrosohexamethyleneimine may occur as a result of the manufacture and use of the chemical. N-Nitrosohexamethyleneimine can be formed in the body in the presence of nitrosating agents from chemicals containing the hexamethyleneimine moiety, such as the hypoglycemic drug tolazamide.

Chemical	CAS No.	Toxicological Endpoints	Listing Mechanism*	Effective Date
Gentian violet (Crystal violet)	548-62-9	Cancer	SQE	November 23, 2018
N-Nitrosohexamethyleneimine	932-83-2	Cancer	SQE	November 23, 2018

* Listing mechanism: SQE - "State's Qualified Expert" mechanism (Health and Safety Code section 25249.8(b) and Title 27, Cal. Code of Regs., section 25305(a)(1)).

Downloads

 [Chemicals Listed as Known to the State of California to Cause Cancer: Gentian Violet and N-Nitrosohexamethyleneimine](#)

Nov 23, 2018

Chemical Reference

- [Gentian Violet](#)
- [N-Nitrosohexamethyleneimine](#)

Footnotes and References

¹¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code section 25249.5 et seq.

Controversy Abounds in Proposed Reproductive Toxicity Amendments

By Jack Schatz | The State of Prop 65 Compliance in 2019

California's Office of Environmental Health Hazard Assessment (OEHHA) recently [proposed amendments](#) to clarify Proposition 65 reproductive toxicity sampling requirements for food products has already stirred up considerable controversy about how the amendments would impact various food products if adopted by the agency.

Proposition 65 prohibits businesses from releasing chemicals "known to the State of California to cause cancer or reproductive toxicity," and from exposing people to chemicals on the [Prop 65 List](#) without providing "clear and reasonable" compliant warnings.

OEHHA's proposed amendments to Title 27, Cal. Code of Regulations, Section 25821, subsections (a) and (c)(2), would change how Prop 65 reproductive toxicity sampling for food products must be tested and calculated.

The controversy concerns the proposed method of calculating exposures to listed reproductive toxicants found in food products.

The proposed amendment to Section 25821, subsection (a) would clarify that where a business presents evidence for the "level in question" of a chemical on the Prop 65 List as causing reproductive toxicity in a food product based on the average of multiple samples of the food product, the level in question may not be calculated by averaging the concentration of the chemical in the food product from different manufacturers or producers of the food product, or that were manufactured in different facilities from the product at issue.

OEHHA's proposed amendment to Section 25821, subsection (c)(2) is intended to clarify how a business should calculate exposures to listed reproductive toxicants and specifies the use of the arithmetic mean as the methodology to be used when calculating the rate of intake or exposure for users of the consumer product.

Previously, until the proposal was introduced by the agency, there had been flexibility for businesses to use the arithmetic or geometric mean; however, this proposal removes that flexibility in favor of a more stringent and rigid approach limiting food companies to calculate risk by the arithmetic mean.

Food companies benefitted greatly from the use of the Geometric mean in the past. Most recently they used this method to prevail in the

Environmental Law Foundation v. Beech-Nut Nutrition Corp., et al. case, in 2013.

The defendants' experts argued successfully that their food products would not cause an exposure to lead above the Safe Harbor level set for lead.

If the recently proposed amendments had been in force at the time it is likely that the outcome in the Beech-Nut trial would have been very different.



Expect the proposed regulation to be hotly disputed.

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